



Case No. 2020-00717-FOIA-OS
American Oversight v. HHS, Civil No. 20-1169

September 7, 2023

Austin Evers
Executive Director
American Oversight
Sent via email: foia@americanoversight.org

Dear Mr. Evers:

This letter is the twenty-eighth interim response to your March 18, 2020, Freedom of Information Act (FOIA) request.

American Oversight requests that HHS produce the following records as soon as practicable, and at least within twenty business days:

All email communications (including email messages, complete email chains, email attachments, calendar invitations) sent by the government officials specified below containing any of the following key terms:

1. Coronavirus
2. Corona
3. Virus
4. Disease
5. Pandemic
6. Epidemic
7. Outbreak
8. containment
9. "public health emergency"
10. "COVID-19"
11. "COVID 19"
12. COVID19
13. SARS
14. "2019-nCoV"
15. POTUS
16. Test
17. Tests
18. Testing
19. EUA
20. Emergency
21. Wuhan
22. Hoax
23. Hubei
24. Princess
25. Cruise
26. Kirkland
27. Seattle
28. "New Rochelle"
29. "BioGen Conference"
30. CPAC
31. AIPAC
32. RNA

33. "Extraction kits"
34. Roche
35. Vaccine
36. Antiviral
37. Antiretroviral
38. Quarantine
39. Distancing
40. Isolation
41. N95
42. Mask
43. Respirator

Government Officials

1. Alex Azar, Secretary
2. Brian Harrison, Chief of Staff
3. Eric Hargan, Deputy Secretary
4. Jerome Adams, Surgeon General
5. Robert Kadlec, Assistant Secretary for Preparedness and Response
6. John Brooks, Senior Advisor to the Secretary for Drug Pricing Reform

On February 10, 2021, you narrowed your request per the following:

Eliminate attachments, documents regarding "Red Dawn" and obvious marketing and news bulletins

- a. Limit the date range of the following key terms as stand-alone search terms from January 15, 2020 through February 29, 2020. ~~[[Limit responsive records to those that also include: (Test OR Tests OR Vaccine OR EUA OR "Emergency Use" OR Shortage OR Shortages OR Supplies OR "the WHO" OR States OR Governor OR Governors OR PPE OR Ventilators OR Respirators OR Swabs OR DPA OR "Defense Production Act" OR Trump OR Pence OR Jared OR Kushner OR "White House" OR "the WH")]]]~~

- i. Coronavirus
- ii. Corona
- iii. "COVID-19"
- iv. "COVID 19"
- v. COVID19
- vi. "2019-nCoV"

~~vii. SARS~~

~~viii. Epidemic~~

~~ix. Pandemic~~

~~x. Outbreak~~

~~xi. "Public Health Emergency"~~

-

- b. After March 1, 2020, for the key terms listed in Column A below (the same search terms as identified above), limit responsive records to those that also include one or more of the terms from Column B:

Column A	Column B
• Coronavirus • Corona • “COVID-19” • “COVID 19” • COVID19 • “2019-nCOV” • SARS • Epidemic • Pandemic • Outbreak • “Public Health Emergency”	• Test • Tests • Vaccine • Antiviral • Antiretroviral • EUA • “Emergency Use” • Shortage • Shortages • Supplies • “Emergency Use” • EUA • “the WHO” • “W.H.O.” • “World Health Organization” • States • Governor • Governors • PPE • Ventilators • Respirators • Swabs • DPA • “Defense Production Act”

- c. For the key terms that are in Column A below, limit responsive records to those that also include one or more of the terms from Column B, for the full time period of the search.

Column A	Column B
• Test • Tests • “Extraction Kits”	• CV19 • “CV-19” • C19 • “C-19” • Roche • RNA • Shortage • Shortages • Supplies • “Emergency Use” • “EUA” • “the WHO” • “W.H.O.” • “World Health Organization” • States • Governor • Governors • Kit • Kits • DPA • “Defense Production Act”

- d. ~~[~500 records] For the key terms that are in Column A below, limit responsive records to those that also include one or more of the terms from Column B, for the full time period of the search.~~

Column A	Column B
---------------------	---------------------

• Vaccine • Antiviral • Antiretroviral	• CV19 • “CV-19” • C19 • “C-19” • “EUA” • “Emergency Use” • “DPA” • “Defense Production Act” • “the WHO” • “W.H.O.” • “World Health Organization”
--	---

c. ~~[<50 records] For the key term “Emergency” limit responsive records to those that also include “DPA” or “Defense Production Act,” for the full time period of the search.~~

f. For the following key terms, please limit the time period as indicated:

i. Princess - February 1, 2020, through March 1, 2020 ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~ii. [~~150 records~~] Kirkland February 24, 2020, through March 24, 2020~~

~~iii. [~~750 records~~] Seattle February 24, 2020, through March 24, 2020~~

~~iv. [~~200 records~~] “New Rochelle” March 1, 2020, through March 31, 2020~~

~~v. [~~<50 records~~] “BioGen Conference” March 1, 2020, through March 31, 2020~~

~~vi. [~~50 records~~] CPAC February 21, 2020, through March 21, 2020~~

~~vii. [~~<50 records~~] AIPAC February 21, 2020, through March 21, 2020~~

g. For the following key terms, please run the search without any modifiers and using the full date range (i.e., no changes from original search)

i. Wuhan ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

ii. Hoax ~~[[no changes]]~~

iii. Hubei ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

iv. POTUS ~~[[no changes]]~~

v. Cruise ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

vi. Quarantine ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

vii. Distancing ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~viii. Isolation~~

ix. N95 ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

x. Mask ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

xi. Respirator ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

xii. Testing ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~xiii. Containment~~

h. Cut the following key terms completely: [[no changes]]

- i. Disease
- ii. Virus

The Department processed **409 pages** of potentially responsive records captured in the agency's search for FOIA request 2020-00717-FOIA-OS. After a careful review of these pages, I have determined to release **151 pages** to you in their entirety and I am further releasing in part **164 pages**, with portions redacted, pursuant to Exemptions (b)(5) and (b)(6) of the FOIA (5 U.S.C. §552 (b)(5) and (b)(6)). Furthermore, I have determined that **94 pages** should be sent for consultation to others and returned to this Department for final disposition.

FOIA exemption (b)(5) protects inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency. This exemption protects documents that would be covered by any privilege an agency could assert in a civil proceeding. These privileges include, among others, the deliberative process privilege, the attorney-client privilege, the attorney work-product privilege and the presidential communications privilege. I have considered the foreseeable harm standard when reviewing these records and applying the (b)(5) exemption.

FOIA exemption (b)(6) permits a federal agency to withhold information and records about individuals in "personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." The definition of "similar files" has historically been broadly interpreted to include a wide variety of files, and the United States Supreme Court has held that Congress intended the term "similar files" to be interpreted broadly, rather than narrowly. I have analyzed these records and find they meet the threshold requirement of this exemption. Additionally, I have reviewed and weighed the public interest in disclosure of this information against the privacy interest in nondisclosure and found that the privacy interest outweighs the public's interest in disclosure.

I have found that it is reasonably foreseeable that disclosure would harm an interest protected by one or more of the exemptions to the FOIA's general rule of disclosure and/or that disclosure is prohibited by law.

We will continue to review the remaining records as efficiently and expeditiously as possible, consistent with our available resources. Should you have questions or concerns regarding the Department's response and/or the processing of your request, any such issues should be communicated to your legal counsel and Department of Justice Attorney representing the Department in this matter.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigation
FOI/Privacy Act Division

Enclosures: 315 pages

From:	HHS Office of Public Affairs <hhsopa@hhs.gov>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	HHS Announces Upcoming Action to Provide Funding to Tribes for COVID-19 Response
Date:	2020/03/20 18:39:07
Priority:	Normal
Type:	Note



U.S. Department of Health and
Human Services

News Release

202-690-6343
media@hhs.gov
www.hhs.gov/news
Twitter [@SpoxHHS](https://twitter.com/SpoxHHS)

FOR IMMEDIATE RELEASE

March 20, 2020

HHS Announces Upcoming Action to Provide Funding to Tribes for COVID-19 Response

Today, the Department of Health and Human Services (HHS) is announcing upcoming action by the Centers for Disease Control and Prevention (CDC) to provide \$80 million in funding to tribes, tribal organizations, and Urban Indian Organizations for resources in support of our nation's response to the 2019 novel coronavirus (COVID-19). This initial action will be followed by additional funding made available on Wednesday, when President Trump signed the Families First Coronavirus Response Act into law, providing additional funds to the Indian Health Service for COVID-19 testing.

"Our nation's tribal health leaders are on the front lines of the COVID-19 outbreak and these additional resources will help increase public health capacity for Indian Country," said CDC Director Robert Redfield. "This virus presents new challenges and our nation's public health infrastructure must have the flexibility to implement public health measures to respond aggressively to the outbreak and to protect all Americans."

As part of this upcoming funding action, CDC will:

- • Supplement an existing CDC Cooperative Agreement to get resources quickly to nine regionally designated tribal organizations, including resources for sub-awards to tribes with the greatest burden and needs in their region and other direct funds to a number of large tribes.
- • Supplement existing funding to the National Council of Urban Indian Health, which will make sub-awards to 41 urban Indian health centers.
- • Supplement existing funding to the National Indian Health Board for COVID-19 communication activities.
- • Issue a new non-competitive grant Notice of Funding Opportunity to reach all Title I and Title V tribes that are eligible to apply for a Federal grant.

For more information about COVID-19, please visit CDC's website:
<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

###

Connect with HHS and sign up for [HHS email updates](#)



[Facebook](#)



[Twitter](#)



[Link to Youtube](#)

If you would rather not receive future communications from U.S. Department of Health and Human Services (HHS), let us know by clicking [here](#).
 U.S. Department of Health and Human Services (HHS), 200 Independence Avenue, SW 6th Floor Room 647-D, Washington, DC 20201 United States

Sender:	HHS Office of Public Affairs <hhsopa@hhs.gov>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/03/20 18:38:32
Delivered Date:	2020/03/20 18:39:07
Message Flags:	Unread

From:	Sherman, Jennifer (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F30FE7FAE664419FA654B20EDCCB1E78-SHERMAN, JE>
To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Subject:	FW: HHS Announces Upcoming Action to Provide Funding to Tribes for COVID-19 Response
Date:	2020/03/20 18:39:59
Priority:	Normal
Type:	Note

FYI

From: HHS Office of Public Affairs <hhsopa@hhs.gov>
Sent: Friday, March 20, 2020 6:39 PM
To: Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>
Subject: HHS Announces Upcoming Action to Provide Funding to Tribes for COVID-19 Response



U.S. Department of Health and
Human Services

News Release

202-690-6343
media@hhs.gov
www.hhs.gov/news
Twitter [@SpoxHHS](https://twitter.com/SpoxHHS)

FOR IMMEDIATE RELEASE
March 20, 2020

HHS Announces Upcoming Action to Provide Funding to Tribes for COVID-19 Response

Today, the Department of Health and Human Services (HHS) is announcing upcoming action by the Centers for Disease Control and Prevention (CDC) to provide \$80 million in funding to tribes, tribal organizations, and Urban Indian Organizations for resources in support of our nation's response to the 2019 novel coronavirus (COVID-19). This initial action will be followed by additional funding made available on Wednesday, when President Trump signed the Families First Coronavirus Response Act into law, providing additional funds to the Indian Health Service for COVID-19 testing.

“Our nation’s tribal health leaders are on the front lines of the COVID-19 outbreak and these additional resources will help increase public health capacity for Indian Country,” said CDC Director Robert Redfield. “This virus presents new challenges and our nation’s public health infrastructure must have the flexibility to implement public health measures to respond aggressively to the outbreak and to protect all Americans.”

As part of this upcoming funding action, CDC will:

- • Supplement an existing CDC Cooperative Agreement to get resources quickly to nine regionally designated tribal organizations, including resources for sub-awards to tribes with the greatest burden and needs in their region and other direct funds to a number of large tribes.
- • Supplement existing funding to the National Council of Urban Indian Health, which will make sub-awards to 41 urban Indian health centers.
- • Supplement existing funding to the National Indian Health Board for COVID-19 communication activities.
- • Issue a new non-competitive grant Notice of Funding Opportunity to reach all Title I and Title V tribes that are eligible to apply for a Federal grant.

For more information about COVID-19, please visit CDC’s website:

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

###

Connect with HHS and sign up for [HHS email updates](#)



Facebook



Twitter



Link to Youtube

If you would rather not receive future communications from U.S. Department of Health and Human Services (HHS), let us know by clicking [here](#).

U.S. Department of Health and Human Services (HHS), 200 Independence Avenue, SW 6th Floor Room 647-D, Washington, DC 20201 United States

Sender:	Sherman, Jennifer (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F30FE7FAE664419FA654B20EDCCB1E78-SHERMAN, JE>
Recipient:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Sent Date:	2020/03/20 18:39:58
Delivered Date:	2020/03/20 18:39:59

From:	Felicia Russell (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:40:34
Priority:	Normal
Type:	Note

Felicia Russell

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Felicia Russell

Sender:	Felicia Russell (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:40:20
Delivered Date:	2020/03/20 18:40:34
Message Flags:	Unread

From:	Aurelia Toyer (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:40:32
Priority:	Normal
Type:	Note

Aurelia Toyer

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Aurelia Toyer

Sender:	Aurelia Toyer (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:40:20
Delivered Date:	2020/03/20 18:40:32
Message Flags:	Unread

From:	Linda Guillet <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:40:30
Priority:	Normal
Type:	Note

Linda Guillet

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Linda Guillet

Sender:	Linda Guillet <linguillet@gmail.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:40:20
Delivered Date:	2020/03/20 18:40:30
Message Flags:	Unread

From:	Rebecca Thompson <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:40:25
Priority:	Normal
Type:	Note

Rebecca Thompson

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Rebecca Thompson

Sender:	Rebecca Thompson <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:40:20
Delivered Date:	2020/03/20 18:40:25
Message Flags:	Unread

From:	Carla Randolph <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:40:41
Priority:	Normal
Type:	Note

Carla Randolph

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Carla Randolph

Sender:	Carla Randolph (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:40:21
Delivered Date:	2020/03/20 18:40:41
Message Flags:	Unread

From:	Janine Mangini (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:40:40
Priority:	Normal
Type:	Note

Janine Mangini

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Janine Mangini, M.D.

Sender:	Janine Mangini (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:40:21
Delivered Date:	2020/03/20 18:40:40
Message Flags:	Unread

From:	Glenda Chambers <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:40:37
Priority:	Normal
Type:	Note

Glenda Chambers

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Glenda Chambers

Sender:	Glenda Chambers <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:40:21
Delivered Date:	2020/03/20 18:40:37
Message Flags:	Unread

From:	Casey Hall <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:55:49
Priority:	Normal
Type:	Note

Casey Hall

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Casey Hall

Sender:	Casey Hall <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:50:22
Delivered Date:	2020/03/20 18:55:49
Message Flags:	Unread

From:	James Wisecarver (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:55:31
Priority:	Normal
Type:	Note

James Wisecarver
983135 Nebraska Medical Center
Omaha, NE 68198-3135

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
James Wisecarver

Sender:	James Wisecarver (b)(6) >
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:50:22
Delivered Date:	2020/03/20 18:55:31
Message Flags:	Unread

From:	MARCUS TIPTON (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:51:51
Priority:	Normal
Type:	Note

MARCUS TIPTON

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

MARCUS TIPTON

Sender:	MARCUS TIPTON (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:50:22
Delivered Date:	2020/03/20 18:51:51
Message Flags:	Unread

From:	Jennifer Mueller <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:51:42
Priority:	Normal
Type:	Note

Jennifer Mueller

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Jennifer Mueller

Sender:	Jennifer Mueller <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:50:22
Delivered Date:	2020/03/20 18:51:42
Message Flags:	Unread

From:	Taoreed Adeoshun (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:51:42
Priority:	Normal
Type:	Note

Taoreed Adeoshun

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Taoreed Adeoshun

Sender:	Taoreed Adeoshun (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:50:22
Delivered Date:	2020/03/20 18:51:42
Message Flags:	Unread

From:	Oluwaseun Williams (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 18:51:32
Priority:	Normal
Type:	Note

Oluwaseun Williams

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Oluwaseun Williams

Sender:	Oluwaseun Williams (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 18:50:22
Delivered Date:	2020/03/20 18:51:32
Message Flags:	Unread

From:	Erica Richardson (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:04:30
Priority:	Normal
Type:	Note

Erica Richardson

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Erica M Richardson, MLS (ASCP)CM

Sender:	Erica Richardson (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:00:24
Delivered Date:	2020/03/20 19:04:30
Message Flags:	Unread

From:	Sheila Prado <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:01:41
Priority:	Normal
Type:	Note

Sheila Prado

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Sheila Prado

Sender:	Sheila Prado <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:00:24
Delivered Date:	2020/03/20 19:01:41
Message Flags:	Unread

From:	Gina Gabriel (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:00:28
Priority:	Normal
Type:	Note

Gina Gabriel

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Gina Gabriel

Sender:	Gina Gabriel (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:00:24
Delivered Date:	2020/03/20 19:00:28
Message Flags:	Unread

From:	Cherry George (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:05:36
Priority:	Normal
Type:	Note

Cherry George

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Cherry George

Sender:	Cherry George (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:00:24
Delivered Date:	2020/03/20 19:05:36
Message Flags:	Unread

From:	Kimberly Hummel (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:10:54
Priority:	Normal
Type:	Note

Kimberly Hummel

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Kimberly Hummel

Sender:	Kimberly Hummel (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:10:24
Delivered Date:	2020/03/20 19:10:54
Message Flags:	Unread

From:	Sandra Tan <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:10:53
Priority:	Normal
Type:	Note

Sandra Tan
(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Sandra Tan

Sender:	Sandra Tan <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:10:25
Delivered Date:	2020/03/20 19:10:53
Message Flags:	Unread

From:	Ruben Garza <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:10:53
Priority:	Normal
Type:	Note

Ruben Garza

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Ruben Garza

Sender:	Ruben Garza <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:10:25
Delivered Date:	2020/03/20 19:10:53
Message Flags:	Unread

From:	Hagir Hamad (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:23:34
Priority:	Normal
Type:	Note

Hagir Hamad

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Hagir Hamad

Sender:	Hagir Hamad (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:20:25
Delivered Date:	2020/03/20 19:23:34
Message Flags:	Unread

From:	Veena Uralil <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:26:08
Priority:	Normal
Type:	Note

Veena Uralil

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Veena Uralil

Sender:	Veena Uralil <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:20:26
Delivered Date:	2020/03/20 19:26:08
Message Flags:	Unread

From:	Rene Brittain (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:25:56
Priority:	Normal
Type:	Note

Rene Brittain

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Rene Brittain

Sender:	Rene Brittain (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:20:26
Delivered Date:	2020/03/20 19:25:56
Message Flags:	Unread

From:	Donald Smith <(b)(6)>
To:	McGowan, Robert (Kyle) (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2046e75239f48a28d2854bedbe5f899-robert.mcgo>; Campbell, Amanda (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93388d67a37747ab956f238181aec3ff-amanda.camp>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	O2MAX BIO Mask
Date:	2020/03/20 19:24:21
Priority:	Normal
Type:	Note

Hello,

We previously have emailed you about our novel oxygen face mask the, O2MAX. In regards to this, Sharp Medical Products, LLC has urgently developed what we believe may be the first truly biological protective simple oxygen mask based on our O2MAX design that has elegantly combined two major functions – medical staff protection and an oxygen supply for ill patients.

The expeditious development of this mask was driven by COVID-19; but this mask will be applicable to patients with any respiratory disease.

With respect to sick patients with respiratory infections (such as COVID-19); many, if not most of these, will be on supplemental oxygen from the EMS arena to the hospital through a simple oxygen mask or nasal cannula. Unfortunately, neither of these devices delivers efficient oxygen or stops the patient from spewing infectious materials (i.e., COVID19 virus) constantly through every one of their exhaled breaths; contaminating the air as well as the surrounding surfaces (ambulance, helicopter, bed, tables etc.). Obviously this creates a dangerous environment for medical personal and families requiring expensive biological containment suits and apprehension. With our mask, not only will the patient receive supplemental oxygen but in addition, we believe, the biological filter system will keep a majority of the infectious materials from leaving the mask – potentially making it much safer for the staff and possibly reducing the need for full containment suits.

Our biological oxygen mask is built using the PVC shell of our revolutionary simple oxygen mask (O2MAX commercially ready) which delivers 50% more oxygen than the market leading face masks; reducing the amount of oxygen required to achieve the same effect; for example, our mask at 5L of oxygen flow per minute results in the same oxygen levels as a standard mask at 10L. This PVC shell is then converted to a biological mask by adding viral level filter material to the air outlets as well as the edges of the mask using a specially designed gasket. The goal is for the exhaled breath to be filtered as much as possible at these two critical areas.

We have also developed a non oxygen supplying mask based on the same design that can be used as PPE for what we believe may be for an extended amount of time vs a disposable paper mask.

The significant outbreak of the COVID-19 virus is taxing the entire healthcare system. We are attempting to do our part as rapidly as possible; due to the complex issues with a rapid spin up of production and raw materials we do not yet have a delivery date – but we can promise we are doing everything we can to bring this to market rapidly. Due to the rapidly evolving nature of this world wide problem, limited time and resources we suggest the following call to action if you are interested in this mask:

1. Provide us with a \$1,500,000 grant to have the O2MAX BIO mask produced and in the hands of those needing it ASAP
2. Use the Defense Production Act to direct industry to prioritize the manufacture and distribution of the O2MAX BIO Mask

Please let me know if there is anything further I can assist with or if you know of someone/agency that you could direct us to further the process along. We request/need and expedited process/path forward to get this into the hands of healthcare personnel immediately.

Best regards,

Don

Donald Smith
Director of Corporate, Government & Military Affairs
Sharp Medical Products, LLC
don.smith@sharpmedicalproducts.com
503-730-0253



Sender:	Donald Smith (b)(6)
Recipient:	McGowan, Robert (Kyle) (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2046e75239f48a28d2854bedbe5f899-robert.mcgo>; Campbell, Amanda (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93388d67a37747ab956f238181aec3ff-amanda.camp>; Berger, Sherri (CDC/OCOO/OD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a9180b08c4a24a48d1d674a7b6b42-Berger, She>; Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:23:48
Delivered Date:	2020/03/20 19:24:21

From:	Diane Wilson (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:30:51
Priority:	Normal
Type:	Note

Diane Wilson

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Diane Wilson, CLS (ASCP)

Sender:	Diane Wilson (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:30:27
Delivered Date:	2020/03/20 19:30:51
Message Flags:	Unread

From:	Shylah Novak <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:30:50
Priority:	Normal
Type:	Note

Shylah Novak

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Shylah Novak

Sender:	Shylah Novak <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:30:27
Delivered Date:	2020/03/20 19:30:50
Message Flags:	Unread

From:	Justine Malave (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:30:49
Priority:	Normal
Type:	Note

Justine Malave

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Justine Malave

Sender:	Justine Malave (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:30:27
Delivered Date:	2020/03/20 19:30:49
Message Flags:	Unread

From:	Allen Pagdilao (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:30:48
Priority:	Normal
Type:	Note

Allen Pagdilao

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Allen Pagdilao

Sender:	Allen Pagdilao (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:30:27
Delivered Date:	2020/03/20 19:30:48
Message Flags:	Unread

From:	Christine Chung (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:30:47
Priority:	Normal
Type:	Note

Christine Chung

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Christine Chung

Sender:	Christine Chung (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:30:27
Delivered Date:	2020/03/20 19:30:47
Message Flags:	Unread

From:	Sarah Bronstein <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:30:47
Priority:	Normal
Type:	Note

Sarah Bronstein

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Sarah Bronstein

Sender:	Sarah Bronstein <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:30:27
Delivered Date:	2020/03/20 19:30:47
Message Flags:	Unread

From:	Kelly Baldwin (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 19:59:03
Priority:	Normal
Type:	Note

Kelly Baldwin

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kelly Baldwin

Sender:	Kelly Baldwin (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:58:41
Delivered Date:	2020/03/20 19:59:03
Message Flags:	Unread

From:	Stephanie Facciolo <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:02:01
Priority:	Normal
Type:	Note

Stephanie Facciolo

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Stephanie Facciolo

Sender:	Stephanie Facciolo <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:58:42
Delivered Date:	2020/03/20 20:02:01
Message Flags:	Unread

From:	Jessica Wells (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:00:51
Priority:	Normal
Type:	Note

Jessica Wells

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Jessica Wells

Sender:	Jessica Wells (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:58:42
Delivered Date:	2020/03/20 20:00:51
Message Flags:	Unread

From:	Ilir Jusufi <ilir.jusufi@cddmedical.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:00:48
Priority:	Normal
Type:	Note

Ilir Jusufi
24806 Catalan Cliff
San Antonio, TX 78261

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Ilir Jusufi

Sender:	Ilir Jusufi <ilir.jusufi@cddmedical.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 19:58:42
Delivered Date:	2020/03/20 20:00:48
Message Flags:	Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.UP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
To:	Disbrow, Gary (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga>
CC:	Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Petillo, Jay (OS/ASPR/MFHC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59ce6133dfa14f6d96b9662b7cfdebc5-Petillo, Ja>; Eldridge, Schuyler (OS/ASPR/MFHC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=102f8b9575fe4272b3a14d43a5cf3f1a-Eldridge, S>; Johnson, Robert (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro>; Acheampong, Otu (OS/ASPR/BARDA) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a96c8cefe54e86a9eccf3b4763431c-Acheampong,>; White, Stephanie M. (OS/ASPR/MFHC) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ae89f65a9ae424485a16cd2668c7629-White, Step>
Subject:	Re: Funding Request
Date:	2020/03/20 20:06:02
Priority:	Normal
Type:	Note

Approved
Kadlec sends.

Sent from my iPhone

On Mar 20, 2020, at 7:42 PM, Disbrow, Gary (OS/ASPR/BARDA)
<Gary.Disbrow@hhs.gov>wrote:

Bob,

Please see below. Que, hand held, in home, near patient diagnostic.

Jay and Bryan concur. Need your approval for NTE \$14M

Gary

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary

Director, Medical Countermeasure Programs

Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR

Department of Health and Human Services

330 Independence Avenue, S.W. Room 640 G

Washington, D.C. 20201

Office: 202-260-0899

Mobile: (b)(6)

Fax: 202-205-0873

email: Gary.Disbrow@HHS.gov

Legally Privileged - This e-mail transmission and any documents attached to it may contain information that is legally privileged. If you are not the intended recipient, or a person responsible for delivering this transmission to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or use of this transmission is strictly prohibited. If you have received this transmission in error, please immediately notify the sender and destroy the original transmission, attachments, and destroy any hard copies.

Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction

From: Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>
Sent: Friday, March 20, 2020 4:13 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Eldridge, Schuyler (OS/ASPR/MFHC) <schuyler.eldridge@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: FW: Funding Request

Dr Kadlec,

BARDA requests an amount NTE \$14M in Covid emergency supplemental funding for the contract action described below. I recommend your approval. Bryan's concurrence also is below.

Please respond by email with your decision.

Jay

(b)(4)

From: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Sent: Friday, March 20, 2020 4:10 PM
To: Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Kemp, Micha (OS/ASPR/MFHC) <Micha.Kemp@hhs.gov>
Subject: Re: Funding Request

Looks good by me

Sent from my iPhone

On Mar 20, 2020, at 4:05 PM, Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@hhs.gov>wrote:

Finance concurs but at this dollar amount I recommend an email approval from Dr Kadlec. Looping in Micha to get this to Bryan's attention.

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Sent: Friday, March 20, 2020 4:02 PM
To: Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: FW: Funding Request

Last one for today

Gary L. Disbrow Ph.D.
Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: 202-260-0899
Mobile: (b)(6)
Fax: 202-205-0873
email: Gary.Disbrow@HHS.gov

Legally Privileged - This e-mail transmission and any documents attached to it may contain information that is legally privileged. If you are not the intended recipient, or a person responsible for delivering this transmission to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or use of this transmission is strictly prohibited. If you have received this transmission in error, please immediately notify the sender and destroy the original transmission, attachments, and destroy any hard copies.

Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the

contractor must disregard that portion of the communication and contact the Contracting Officer for direction

From: Disbrow, Gary (OS/ASPR/BARDA)
Sent: Friday, March 20, 2020 2:24 PM
To: Petillo, Jay (OS/ASPR/OFPA) (<Jay.Petillo@HHS.GOV> <Jay.Petillo@HHS.GOV>); Shuy, Bryan (OS/ASPR/IO) (<Bryan.Shuy@hhs.gov> <Bryan.Shuy@hhs.gov>
Cc: Disbrow, Gary (OS/ASPR/BARDA) (<Gary.Disbrow@hhs.gov>); Johnson, Robert (OS/ASPR/BARDA) (<Robert.Johnson@hhs.gov> <Robert.Johnson@hhs.gov>); Houchens, Christopher (HHS/ASPR) (<Christopher.Houchens@hhs.gov> <Christopher.Houchens@hhs.gov>); Bright, Rick (OS/ASPR/BARDA) (<Rick.Bright@hhs.gov>); Acheampong, Otuo (OS/ASPR/BARDA) (CTR) (<Otuo.Acheampong@hhs.gov>); Blatner, Gretta (OS/ASPR/BARDA) (<Gretta.Blatner@hhs.gov> <Gretta.Blatner@hhs.gov>); Oshansky, Christine (OS/ASPR/BARDA) (<Christine.Oshansky@hhs.gov>
Subject: Funding Request

Jay and Bryan,

Please see the below information for a funding request for COVID-19. Next week is going to be a busy week with these and I will try to limit emails to a Monday, Wednesday, Friday tempo. (b)(5)

(b)(5)

(b)(5)

Thank you both for the support and Jay your team is doing a great job working with us.

(b)(4)

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201

Office: 202-260-0899
Mobile: (b)(6)
Fax: 202-205-0873
email: Gary.Disbrow@HHS.gov

Legally Privileged - This e-mail transmission and any documents attached to it may contain information that is legally privileged. If you are not the intended recipient, or a person responsible for delivering this transmission to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or use of this transmission is strictly prohibited. If you have received this transmission in error, please immediately notify the sender and destroy the original transmission, attachments, and destroy any hard copies.

Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction

Sender:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
Recipient:	Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Petillo, Jay (OS/ASPR/MFHC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59ce6133dfa14f6d96b9662b7cfdebc5-Petillo, Ja>; Eldridge, Schuyler (OS/ASPR/MFHC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=102f8b9575fe4272b3a14d43a5cf3f1a-Eldridge, S>; Johnson, Robert (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro>; Acheampong, Otuoh (OS/ASPR/BARDA) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a96c8cfe54e86a9eccf3b4763431c-Acheampong,>; White, Stephanie M. (OS/ASPR/MFHC) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ae89f65a9ae424485a16cd2668c7629-White, Step>; Disbrow, Gary (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga>
Sent Date:	2020/03/20 20:06:02

From:	Christina Carter (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:13
Priority:	Normal
Type:	Note

Christina Carter

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Christina Carter

Sender:	Christina Carter (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:45
Delivered Date:	2020/03/20 20:09:13
Message Flags:	Unread

From:	Latanya Jackson (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:11
Priority:	Normal
Type:	Note

Latanya Jackson

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Latanya Jackson

Sender:	Latanya Jackson (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:45
Delivered Date:	2020/03/20 20:09:11
Message Flags:	Unread

From:	Sarah Schwartz <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:09
Priority:	Normal
Type:	Note

Sarah Schwartz

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Sarah Schwartz

Sender:	Sarah Schwartz <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:45
Delivered Date:	2020/03/20 20:09:09
Message Flags:	Unread

From:	Kurt Nolte (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:06
Priority:	Normal
Type:	Note

Kurt Nolte

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kurt Nolte

Sender:	Kurt Nolte (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:45
Delivered Date:	2020/03/20 20:09:06
Message Flags:	Unread

From:	Angela Boyer (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:38
Priority:	Normal
Type:	Note

Angela Boyer

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Angela Boyer

Sender:	Angela Boyer (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:46
Delivered Date:	2020/03/20 20:09:38
Message Flags:	Unread

From:	April Williams (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:19
Priority:	Normal
Type:	Note

April Williams

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
April Williams

Sender:	April Williams (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:46
Delivered Date:	2020/03/20 20:09:19
Message Flags:	Unread

From:	Michael Potoski <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:19
Priority:	Normal
Type:	Note

Michael Potoski

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Michael Potoski

Sender:	Michael Potoski <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:46
Delivered Date:	2020/03/20 20:09:19
Message Flags:	Unread

From:	Chau Dang (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:09:19
Priority:	Normal
Type:	Note

Chau Dang

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Chau Dang

Sender:	Chau Dang (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:08:46
Delivered Date:	2020/03/20 20:09:19
Message Flags:	Unread

From:	Thomas Bladek <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:19:19
Priority:	Normal
Type:	Note

Thomas Bladek

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Thomas Bladek

Sender:	Thomas Bladek <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:18:47
Delivered Date:	2020/03/20 20:19:19
Message Flags:	Unread

From:	Nancy Martin <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:19:18
Priority:	Normal
Type:	Note

Nancy Martin

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Nancy Martin

Sender:	Nancy Martin <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:18:47
Delivered Date:	2020/03/20 20:19:18
Message Flags:	Unread

From:	Trueman, Laura (HHS/IEA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA>
To:	Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcb4c6ea342c08d58f63e37d997e7-Trueeman, La>
Subject:	HHS Updates: COVID-19
Date:	2020/03/20 20:21:26
Priority:	Normal
Type:	Note

Dear Colleague:

I missed communicating with you last week. One reason - COVID-19. This week's update outlines how we continue to respond to the ever-changing COVID-19 pandemic, plus some regular HHS business.

COVID-19 – Many New Guidances & Information Released

Who are the “Essential Workers”? Recently an association in the medical supply chain said that their members were concerned because while healthcare workers were clearly “essential workers,” states were not recognizing their businesses and employees as critical. This week, the Department of Homeland Security issued a [Guidance](#) on who is critical to the nation's infrastructure. It is not mandatory, it is guidance. And yes, “supply chain workforce” is included in their list of “essential critical infrastructure workers.”

Expanding Testing Capabilities: On Monday night, FDA Commissioner Hahn [announced](#) that states can set up their own system in which they take responsibility for authorizing tests and the laboratories will not need to engage with the FDA to conduct COVID-19 testing. The updated guidance also expands the types of labs that can conduct testing and provides recommendations for test developers who are interested in developing a test. The FDA has established 1-888-INFO-FDA, to help labs with any questions they may have about the Emergency Use Authorization process, FDA policies or getting supplies. Similar to approving Roche testing last week, the FDA also [issued Emergency Use Authorizations \(EUAs\)](#) to Hologic and LabCorp for their tests.

New Telehealth Benefits: The Trump Administration and HHS announced unprecedented steps to expand Americans' access to telehealth during the COVID-19 outbreak. The Centers for Medicare & Medicaid Services (CMS) expanded Medicare coverage for telehealth visits, the HHS Office for Civil Rights (OCR) announced it will waive potential HIPAA penalties for good faith use of telehealth during the emergency, and the HHS Office of Inspector General (OIG) provided flexibility for healthcare providers to reduce or waive beneficiary cost-sharing for telehealth visits paid by federal healthcare programs. For more information see links to the [CMS press release](#), [OCR Guidance](#), and [OIG Policy Statement](#).

Restrictions on Gatherings: On Monday, the White House Task Force released [updated guidance](#) with a 15 day strategy to slow the spread of COVID-19 that recommends restricting gatherings to 10 people or less.

Helping Communities Know Mitigation Strategies: Last Tuesday, CDC released their “[Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission](#).” Essentially, this is a guide describing possible mitigation strategies for communities dealing with transmission at three different levels: (1) None/Minimal, (2) Moderate, or (3) Substantial. The Community Mitigation Plan can be found [here](#).

Telehealth Toolkits for General Practitioners and End-Stage Renal Disease Providers: CMS released two toolkits today to help practitioners understand the broadened access to Medicare telehealth services so that beneficiaries can receive a wider range of services from their doctors without having to travel to a healthcare facility. Under this new waiver, Medicare can pay for office, hospital, and other visits furnished via telehealth across the country and including in patient’s places of residence starting March 6, 2020. A range of providers, such as doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers, will be able to offer telehealth to their patients. The toolkit for General Practitioners can be found [here](#) and for ESRD providers [here](#).

Resources for Business and Employers: Includes cleaning and disinfection recommendations, preparing your workplace for COVID-19, and strategies to respond if employees become infected. The webpage can be found [here](#). As part of this resource, CDC released interim guidance to help prevent workplace exposures to acute respiratory illnesses, including COVID-19, in non-healthcare settings. The guidance also provides planning considerations if there are more widespread, community outbreaks of COVID-19. The guidance can be found [here](#).

CMS Approves Washington 1135 Waiver: Washington is the second state to receive [1135 waiver approval](#) from CMS for flexibilities that enable the state to focus its resources on combatting the outbreak and provide the best possible care to Medicaid beneficiaries in their state. More information on 1135 waivers can be found [here](#).

COVID-19: What People with HIV Should Know: Although the risk of serious illness from COVID-19 for people with HIV is not known, people with HIV may have concerns and questions related to their risk. To address these concerns CDC released information available [here](#).

FDA Allows Expanded Use of Devices to Monitor Patients’ Vital Signs Remotely: FDA issued a new policy that allows manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate and blood pressure. The guidance can be found [here](#).

General Preparation Information: On March 9, 2020, the White House Coronavirus Task Force released practical steps that we recommend posting and sharing to keep workplaces, school, home and commercial establishments safe. This information can be found [here](#).

Phase 1 of Vaccine Trial: On Monday, the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health announced that a Phase 1 clinical trial evaluating an investigational vaccine designed to protect against COVID-19 has begun at Kaiser Permanente Washington Health Research Institute in Seattle, funded by NIH. More information can be found [here](#).

Recommended Preventive Practices and FAQs for Faith-based and Community Leaders: HHS recognizes faith and community leaders are a valuable source of comfort and support for members and communities during times of distress, including the growing presence of COVID-19 in different parts of the U.S. To support these efforts, the HHS Partnership Center released a [FAQ document](#) on COVID-19 for this population.

HHS Expanding Public-Private Partnerships: HHS announced a public-private partnership to create a U.S.-based, high-speed, high-volume emergency drug packaging solution using low-cost prefilled syringes. This partnership will enable the Strategic National Stockpile (SNS) to fill and finish, on a rapid basis, hundreds of millions of prefilled syringes to respond quickly and efficiently to widespread health emergencies, such as the novel coronavirus outbreak. More information can be found [here](#).

Key Leaders with Messages: Key leaders have written or taped short videos to explain different roles and responsibilities for individuals as part of community mitigation.

- Vice President Pence Asking for American People's Help to Fight Coronavirus ([Op-Ed](#))
- Dr. Fauci on What is Social Distancing? ([Video](#))
- Surgeon General Message to Millennials ([Video](#))
- CDC's Dr. Jay Butler on What Older Adults Need to Know ([Video](#))
- Ambassador Bix on Who Needs to be Tested for Coronavirus ([Video](#))

More Guidance and FAQs:

- [CDC Guidance on Infection Control for Healthcare Workers](#)
- [CDC FAQ website for Laboratories](#)
- [CDC Guidance on Evaluating and Testing Persons for COVID-19](#)
- [CDC Guidance for Discontinuation of Home Isolation for Persons with COVID-19](#)
- [FDA FAQ on Food Safety](#)
- [CMS Nursing Home Guidance](#)
- All CMS guidance related to COVID-19 can be found [here](#).

New updates and guidance come out constantly, so as always, I encourage you to visit resources like [CDC's website on COVID-19](#) for the most up to date information.

Noteworthy Meetings...

Secretary Azar and the American Association of Nurse Practitioners

On March 10th, the Secretary delivered [remarks](#) to the American Association of Nurse Practitioner's at their Annual Health Policy Conference. He gave a brief update on COVID-19 and thanked them for the important role they are playing on the front lines of this response. He also spoke about their role in the Administration's Health Care Vision and how vital nurse practitioners are, especially to rural America.

Deputy Secretary Hargan met with United Airlines CEO

On Tuesday, Deputy Secretary Eric Hargan met with United Airlines CEO Oscar Munoz to discuss the impact of COVID-19 on airlines and travel.

The American Red Cross

Also on Tuesday, Deputy Secretary Hargan along with Surgeon General Jerome Adams spoke with members of the American Red Cross to discuss the importance of continual blood donation during the

COVID-19 crisis. The American Red Cross supplies roughly 40% of the donated blood in the United States, and recently has seen a significant drop in the number of blood donations. American Red Cross members have been engaging with various HHS officials on amplifying the need for healthy Americans to continue to donate blood. Please visit the [American Red Cross website](#) if you would like to learn more.

Secretary's Tele-TownHall Meeting with Hospitals

On Thursday evening, the Secretary hosted a tele-townhall with hospitals from across the nation. Leadership from two hospitals – Providence St. Joseph in Seattle and Kaiser Permanente in California – which have been ground zero for COVID-19. These two hospital leaders shared lessons learned with more than 2000 of their peers. Secretary Azar believes that real time knowledge transfer is helpful as other communities gear up for increased cases.

In Other News...

Interoperability

On March 9th, the Department [released](#) the two final Interoperability rules. Together, these final rules mark the most extensive healthcare data sharing policies the federal government has implemented, requiring both public and private entities to share health information between patients and other parties while keeping that information private and secure, a top priority for the Administration. The two rules, issued by ONC and CMS, implement interoperability and patient access provisions of the bipartisan 21st Century Cures Act ([Cures Act](#)) and support President Trump's [MyHealthEData initiative](#) announced back in March 2018. MyHealthEData is designed to empower patients around a common aim - giving every American access to their medical information so they can make better healthcare decisions.

[CMS final rule](#) and the [ONC final rule](#).

Op-ed written by Jared Kushner, Seema Verma and Don Rucker [here](#).

Thank you for your work on COVID-19 and other health issues facing the country. Many of you have checked in to see how we are all holding up. No doubt this is intense. However, we are aware that we are living history, that what we do has direct bearing on arming people to make good choices and have the information needed to protect themselves, their loved ones, their employees and friends. That is high motivation. Be healthy.

Laura Trueman

Laura C. Trueman
Director, Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington D.C. 20201
Laura.Trueman@hhs.gov
202-690-6060 (main office)

Sender: Trueman, Laura (HHS/IEA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA>
Recipient:	Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcba4c6ea342c08d58f63e37d997e7-Trueman, La>
Sent Date:	2020/03/20 20:21:23
Delivered Date:	2020/03/20 20:21:26

From:	Trueman, Laura (HHS/IEA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA>
To:	Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcb4c6ea342c08d58f63e37d997e7-Trueeman, La>
Subject:	HHS Updates: COVID-19
Date:	2020/03/20 20:21:25
Priority:	Normal
Type:	Note

Dear Colleague:

I missed communicating with you last week. One reason - COVID-19. This week's update outlines how we continue to respond to the ever-changing COVID-19 pandemic, plus some regular HHS business.

COVID-19 – Many New Guidances & Information Released

Who are the “Essential Workers”? Recently an association in the medical supply chain said that their members were concerned because while healthcare workers were clearly “essential workers,” states were not recognizing their businesses and employees as critical. This week, the Department of Homeland Security issued a [Guidance](#) on who is critical to the nation's infrastructure. It is not mandatory, it is guidance. And yes, “supply chain workforce” is included in their list of “essential critical infrastructure workers.”

Expanding Testing Capabilities: On Monday night, FDA Commissioner Hahn [announced](#) that states can set up their own system in which they take responsibility for authorizing tests and the laboratories will not need to engage with the FDA to conduct COVID-19 testing. The updated guidance also expands the types of labs that can conduct testing and provides recommendations for test developers who are interested in developing a test. The FDA has established 1-888-INFO-FDA, to help labs with any questions they may have about the Emergency Use Authorization process, FDA policies or getting supplies. Similar to approving Roche testing last week, the FDA also [issued Emergency Use Authorizations \(EUAs\)](#) to Hologic and LabCorp for their tests.

New Telehealth Benefits: The Trump Administration and HHS announced unprecedented steps to expand Americans' access to telehealth during the COVID-19 outbreak. The Centers for Medicare & Medicaid Services (CMS) expanded Medicare coverage for telehealth visits, the HHS Office for Civil Rights (OCR) announced it will waive potential HIPAA penalties for good faith use of telehealth during the emergency, and the HHS Office of Inspector General (OIG) provided flexibility for healthcare providers to reduce or waive beneficiary cost-sharing for telehealth visits paid by federal healthcare programs. For more information see links to the [CMS press release](#), [OCR Guidance](#), and [OIG Policy Statement](#).

Restrictions on Gatherings: On Monday, the White House Task Force released [updated guidance](#) with a 15 day strategy to slow the spread of COVID-19 that recommends restricting gatherings to 10 people or less.

Helping Communities Know Mitigation Strategies: Last Tuesday, CDC released their “[Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission](#).” Essentially, this is a guide describing possible mitigation strategies for communities dealing with transmission at three different levels: (1) None/Minimal, (2) Moderate, or (3) Substantial. The Community Mitigation Plan can be found [here](#).

Telehealth Toolkits for General Practitioners and End-Stage Renal Disease Providers: CMS released two toolkits today to help practitioners understand the broadened access to Medicare telehealth services so that beneficiaries can receive a wider range of services from their doctors without having to travel to a healthcare facility. Under this new waiver, Medicare can pay for office, hospital, and other visits furnished via telehealth across the country and including in patient’s places of residence starting March 6, 2020. A range of providers, such as doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers, will be able to offer telehealth to their patients. The toolkit for General Practitioners can be found [here](#) and for ESRD providers [here](#).

Resources for Business and Employers: Includes cleaning and disinfection recommendations, preparing your workplace for COVID-19, and strategies to respond if employees become infected. The webpage can be found [here](#). As part of this resource, CDC released interim guidance to help prevent workplace exposures to acute respiratory illnesses, including COVID-19, in non-healthcare settings. The guidance also provides planning considerations if there are more widespread, community outbreaks of COVID-19. The guidance can be found [here](#).

CMS Approves Washington 1135 Waiver: Washington is the second state to receive [1135 waiver approval](#) from CMS for flexibilities that enable the state to focus its resources on combatting the outbreak and provide the best possible care to Medicaid beneficiaries in their state. More information on 1135 waivers can be found [here](#).

COVID-19: What People with HIV Should Know: Although the risk of serious illness from COVID-19 for people with HIV is not known, people with HIV may have concerns and questions related to their risk. To address these concerns CDC released information available [here](#).

FDA Allows Expanded Use of Devices to Monitor Patients’ Vital Signs Remotely: FDA issued a new policy that allows manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate and blood pressure. The guidance can be found [here](#).

General Preparation Information: On March 9, 2020, the White House Coronavirus Task Force released practical steps that we recommend posting and sharing to keep workplaces, school, home and commercial establishments safe. This information can be found [here](#).

Phase 1 of Vaccine Trial: On Monday, the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health announced that a Phase 1 clinical trial evaluating an investigational vaccine designed to protect against COVID-19 has begun at Kaiser Permanente Washington Health Research Institute in Seattle, funded by NIH. More information can be found [here](#).

Recommended Preventive Practices and FAQs for Faith-based and Community Leaders: HHS recognizes faith and community leaders are a valuable source of comfort and support for members and communities during times of distress, including the growing presence of COVID-19 in different parts of the U.S. To support these efforts, the HHS Partnership Center released a [FAQ document](#) on COVID-19 for this population.

HHS Expanding Public-Private Partnerships: HHS announced a public-private partnership to create a U.S.-based, high-speed, high-volume emergency drug packaging solution using low-cost prefilled syringes. This partnership will enable the Strategic National Stockpile (SNS) to fill and finish, on a rapid basis, hundreds of millions of prefilled syringes to respond quickly and efficiently to widespread health emergencies, such as the novel coronavirus outbreak. More information can be found [here](#).

Key Leaders with Messages: Key leaders have written or taped short videos to explain different roles and responsibilities for individuals as part of community mitigation.

- Vice President Pence Asking for American People's Help to Fight Coronavirus ([Op-Ed](#))
- Dr. Fauci on What is Social Distancing? ([Video](#))
- Surgeon General Message to Millennials ([Video](#))
- CDC's Dr. Jay Butler on What Older Adults Need to Know ([Video](#))
- Ambassador Birx on Who Needs to be Tested for Coronavirus ([Video](#))

More Guidance and FAQs:

- [CDC Guidance on Infection Control for Healthcare Workers](#)
- [CDC FAQ website for Laboratories](#)
- [CDC Guidance on Evaluating and Testing Persons for COVID-19](#)
- [CDC Guidance for Discontinuation of Home Isolation for Persons with COVID-19](#)
- [FDA FAQ on Food Safety](#)
- [CMS Nursing Home Guidance](#)
- All CMS guidance related to COVID-19 can be found [here](#).

New updates and guidance come out constantly, so as always, I encourage you to visit resources like [CDC's website on COVID-19](#) for the most up to date information.

Noteworthy Meetings...

Secretary Azar and the American Association of Nurse Practitioners

On March 10th, the Secretary delivered [remarks](#) to the American Association of Nurse Practitioner's at their Annual Health Policy Conference. He gave a brief update on COVID-19 and thanked them for the important role they are playing on the front lines of this response. He also spoke about their role in the Administration's Health Care Vision and how vital nurse practitioners are, especially to rural America.

Deputy Secretary Hargan met with United Airlines CEO

On Tuesday, Deputy Secretary Eric Hargan met with United Airlines CEO Oscar Munoz to discuss the impact of COVID-19 on airlines and travel.

The American Red Cross

Also on Tuesday, Deputy Secretary Hargan along with Surgeon General Jerome Adams spoke with members of the American Red Cross to discuss the importance of continual blood donation during the

COVID-19 crisis. The American Red Cross supplies roughly 40% of the donated blood in the United States, and recently has seen a significant drop in the number of blood donations. American Red Cross members have been engaging with various HHS officials on amplifying the need for healthy Americans to continue to donate blood. Please visit the [American Red Cross website](#) if you would like to learn more.

Secretary's Tele-TownHall Meeting with Hospitals

On Thursday evening, the Secretary hosted a tele-townhall with hospitals from across the nation. Leadership from two hospitals – Providence St. Joseph in Seattle and Kaiser Permanente in California – which have been ground zero for COVID-19. These two hospital leaders shared lessons learned with more than 2000 of their peers. Secretary Azar believes that real time knowledge transfer is helpful as other communities gear up for increased cases.

In Other News...

Interoperability

On March 9th, the Department [released](#) the two final Interoperability rules. Together, these final rules mark the most extensive healthcare data sharing policies the federal government has implemented, requiring both public and private entities to share health information between patients and other parties while keeping that information private and secure, a top priority for the Administration. The two rules, issued by ONC and CMS, implement interoperability and patient access provisions of the bipartisan 21st Century Cures Act ([Cures Act](#)) and support President Trump's [MyHealthEData initiative](#) announced back in March 2018. MyHealthEData is designed to empower patients around a common aim - giving every American access to their medical information so they can make better healthcare decisions.

[CMS final rule](#) and the [ONC final rule](#).

Op-ed written by Jared Kushner, Seema Verma and Don Rucker [here](#).

Thank you for your work on COVID-19 and other health issues facing the country. Many of you have checked in to see how we are all holding up. No doubt this is intense. However, we are aware that we are living history, that what we do has direct bearing on arming people to make good choices and have the information needed to protect themselves, their loved ones, their employees and friends. That is high motivation. Be healthy.

Laura Trueman

Laura C. Trueman
Director, Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington D.C. 20201
Laura.Trueman@hhs.gov
202-690-6060 (main office)

Sender: Trueman, Laura (HHS/IEA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA>
Recipient:	Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcba4c6ea342c08d58f63e37d997e7-Trueman, La>
Sent Date:	2020/03/20 20:21:23
Delivered Date:	2020/03/20 20:21:25

From:	Dulaigh, Joel (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02B15E96DC484DB29682C1D336E63441-DULAIGH, JO>
To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Subject:	PHR supplemental request for Dep Sec
Date:	2020/03/20 20:25:43
Priority:	Normal
Type:	Note

Sir,

For your review. I have attached the file, but have also embedded the text below in case it is easier to read on your phone.

ISSUE:

(b)(5)

BACKGROUND:

(b)(5)

(b)(5)

REQUEST:

(b)(5)

V/R,
Joel

CAPT Joel Dulaigh, ACNP-BC, FAANP
Chief of Staff to the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
200 Independence Ave SW, Suite 701-H
Washington, DC 20201
Office Phone: 202-690-7511
Cell: (b)(6)
Direct Fax: 202.260.4405
Email: joel.dulaigh@hhs.gov

In Officio Salutis

Sender:	Dulaigh, Joel (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02B15E96DC484DB29682C1D336E63441-DULAIGH, JO>
Recipient:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Sent Date:	2020/03/20 20:25:41
Delivered Date:	2020/03/20 20:25:43

From:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
To:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	IOS Nightly Update
Date:	2020/03/20 20:27:53
Priority:	Normal
Type:	Note

Sent to White House (Night Note):

None

Other Newsworthy Items:

- On Saturday, CMS will send the COVID Exchange SEP Press Release
- On Monday, CDC's successful Tips From Former Smokers campaign returns

From Today:

- (CMS) [CMS Approves Washington State's Request for 1135 Medicaid Waivers](#)
- (FDA) [Coronavirus \(COVID-19\) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits](#)
- (FDA) [Coronavirus \(COVID-19\) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health](#)
- (FDA) [Coronavirus \(COVID-19\) Update: FDA allows expanded use of devices to monitor patients' vital signs remotely](#)
- (NIH) [NIH shifts non-mission-critical laboratory operations to minimal maintenance phase](#)

Notable Coverage:

Community health centers worried about mask shortage closing their doors
Twin Cities Pioneer Press // Frederick Melo

Noem to Trump: State had to get 'pushy' for chemical to run coronavirus tests
Sioux Falls Argus Leader // Jonathan Ellis

U.S.-Mexico Border to Close Amid Coronavirus Spread
US News & World Report // Claire Hansen

Sender:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
Recipient:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/03/20 20:27:52
Delivered Date:	2020/03/20 20:27:53

From:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
To:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	IOS Nightly Update
Date:	2020/03/20 20:27:53
Priority:	Normal
Type:	Note

Sent to White House (Night Note):

None

Other Newsworthy Items:

- On Saturday, CMS will send the COVID Exchange SEP Press Release
- On Monday, CDC's successful Tips From Former Smokers campaign returns

From Today:

- (CMS) [CMS Approves Washington State's Request for 1135 Medicaid Waivers](#)
- (FDA) [Coronavirus \(COVID-19\) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits](#)
- (FDA) [Coronavirus \(COVID-19\) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health](#)
- (FDA) [Coronavirus \(COVID-19\) Update: FDA allows expanded use of devices to monitor patients' vital signs remotely](#)
- (NIH) [NIH shifts non-mission-critical laboratory operations to minimal maintenance phase](#)

Notable Coverage:

Community health centers worried about mask shortage closing their doors
Twin Cities Pioneer Press // Frederick Melo

Noem to Trump: State had to get 'pushy' for chemical to run coronavirus tests
Sioux Falls Argus Leader // Jonathan Ellis

U.S.-Mexico Border to Close Amid Coronavirus Spread
US News & World Report // Claire Hansen

Sender:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
Recipient:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/03/20 20:27:52
Delivered Date:	2020/03/20 20:27:53
Message Flags:	Unread

From:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
To:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>
CC:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	Secretary's Nightly Update
Date:	2020/03/20 20:28:22
Priority:	Normal
Type:	Note

Sent to White House (Night Note):

None

Other Newsworthy Items:

- On Saturday, CMS will send the COVID Exchange SEP Press Release
- On Monday, CDC's successful Tips From Former Smokers campaign returns

From Today:

- (CMS) CMS Approves Washington State's Request for 1135 Medicaid Waivers
- (FDA) Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits
- (FDA) Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health
- (FDA) Coronavirus (COVID-19) Update: FDA allows expanded use of devices to monitor patients' vital signs remotely

- (NIH) NIH shifts non-mission-critical laboratory operations to minimal maintenance phase

Notable Coverage:

Community health centers worried about mask shortage closing their doors
Twin Cities Pioneer Press // Frederick Melo

Noem to Trump: State had to get 'pushy' for chemical to run coronavirus tests
Sioux Falls Argus Leader // Jonathan Ellis

U.S.-Mexico Border to Close Amid Coronavirus Spread
US News & World Report // Claire Hansen

Sender:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
Recipient:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/20 20:28:21
Delivered Date:	2020/03/20 20:28:22

From:	April Bell <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:28:52
Priority:	Normal
Type:	Note

April Bell

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
April Bell

Sender:	April Bell <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:28:47
Delivered Date:	2020/03/20 20:28:52
Message Flags:	Unread

From:	Geoffrey Sensel <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:29:03
Priority:	Normal
Type:	Note

Geoffrey Sensel

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Geoffrey Sensel

Sender:	Geoffrey Sensel <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:28:47
Delivered Date:	2020/03/20 20:29:03
Message Flags:	Unread

From:	Kimberly Bersell (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:28:58
Priority:	Normal
Type:	Note

Kimberly Bersell

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Kimberly Bersell

Sender:	Kimberly Bersell (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:28:48
Delivered Date:	2020/03/20 20:28:58
Message Flags:	Unread

From:	Janet Olmeda-Dávila (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:28:53
Priority:	Normal
Type:	Note

Janet Olmeda-Dávila

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Janet Olmeda-Dávila

Sender:	Janet Olmeda-Dávila (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:28:48
Delivered Date:	2020/03/20 20:28:53
Message Flags:	Unread

From:	Kristina Huddleston (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:38:56
Priority:	Normal
Type:	Note

Kristina Huddleston

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kristina Huddleston

Sender:	Kristina Huddleston (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:38:50
Delivered Date:	2020/03/20 20:38:56
Message Flags:	Unread

From:	Akhtar Shamshair <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:38:56
Priority:	Normal
Type:	Note

Akhtar Shamshair

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Akhtar Shamshair

Sender:	Akhtar Shamshair <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:38:50
Delivered Date:	2020/03/20 20:38:56
Message Flags:	Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D145EFC9C35C4865ACA6E9D47786B204-HARRISON, B>
To:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>
CC:	Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	Fwd: Email to Secretary Azar re: Genentech Actemra Donation
Date:	2020/03/20 20:47:11
Priority:	Normal
Type:	Note

Begin forwarded message:

From: Jennifer Young <jyoung@tdyllc.com>
Date: March 20, 2020 at 8:43:30 PM EDT
To: "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>, "Steele, Danielle (HHS/IOS)" <Danielle.Steele@hhs.gov>
Subject: Email to Secretary Azar re: Genentech Actemra Donation

Please see below from the CEO of Genentech, announcing a donation to the stockpile of one of their medicines that has been helpful in China and Italy. We will work directly with ASPR, but we wanted you all to know as well. Please share with the Secretary as you deem appropriate.
 With thanks,
 Jennifer

Dear Secretary Azar:

As part of Genentech and the Roche Group's ongoing commitment to support the United States Government's (USG) response to the COVID-19 pandemic, I am writing to inform you of our intent to donate 10,000 vials of Actemra (tocilizumab) to the Strategic National Stockpile (SNS) to support future use at the discretion of the USG. I plan to follow-up directly with HHS Assistant Secretary for Preparedness and Response Dr. Robert Kadlec, BARDA Director Dr. Rick Bright, and SNS Head Victor Harper to formally offer the donation for virtual stockpile in the SNS. We greatly appreciate the partnership with HHS, and given the importance of activities around this pandemic, I will make myself or others on my team available to you or members of your team, as needed.

Sincerely,



image.png

Alexander Hardy

CEO Genentech, Inc.

(b)(6) mobile

hardy.alexander@gene.com

Background

Actemra, an FDA-approved immunosuppressant biologic drug that targets the interleukin 6 (IL-6) receptor, has been used to treat severely ill COVID-19 patients with trouble breathing and elevated IL-6 levels in China, Italy, Switzerland, and other nations. Despite anecdotal reports from China and Italy, there are no robust, well-controlled studies showing safety and efficacy of Actemra in the clinical treatment of patients with COVID-19 pneumonia. Today, we received approval from the FDA Division of Antivirals (DAV) related to an Investigational New Drug Application (IND) to investigate the use of Actemra for the treatment of hospitalized patients with severe COVID-19 pneumonia in collaboration with Biomedical Advanced Research and Development Authority (BARDA).

We are committed to investigating this use of Actemra, but given our global experience, we also believe there will be a more acute need to ensure availability of treatment in certain immediate cases deemed clinically appropriate. We have seen a sharp increase in the number of inquiries from government entities in many countries about the availability of Actemra for the treatment of patients with severe COVID-19 pneumonia, and we believe this donation to the USG is a critical step in preparing for expected future demand for emergency treatment in the United States. This donation will be made to backfill supply from our clinical study and to support future use at the discretion of the USG.

Sender:	Harrison, Brian (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D145EFC9C35C4865ACA6E9D47786B204-HARRISON, B>
Recipient:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/03/20 20:47:10
Delivered Date:	2020/03/20 20:47:11

From:	Michal Kamionek (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:58:52
Priority:	Normal
Type:	Note

Michal Kamionek

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Michal Kamionek

Sender:	Michal Kamionek (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:48:51
Delivered Date:	2020/03/20 20:58:52
Message Flags:	Unread

From:	Ronald McKinley <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:58:50
Priority:	Normal
Type:	Note

Ronald McKinley

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Ronald McKinley

Sender:	Ronald McKinley <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:48:51
Delivered Date:	2020/03/20 20:58:50
Message Flags:	Unread

From:	Natalie Chapman <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:58:50
Priority:	Normal
Type:	Note

Natalie Chapman

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Natalie Chapman

Sender:	Natalie Chapman <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:48:51
Delivered Date:	2020/03/20 20:58:50
Message Flags:	Unread

From:	Brian Foster (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:58:50
Priority:	Normal
Type:	Note

Brian Foster

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Brian Foster

Sender:	Brian Foster (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:48:51
Delivered Date:	2020/03/20 20:58:50
Message Flags:	Unread

From:	Angela Gabelbauer <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:56:28
Priority:	Normal
Type:	Note

Angela Gabelbauer

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Angela Gabelbauer

Sender:	Angela Gabelbauer <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:48:51
Delivered Date:	2020/03/20 20:56:28
Message Flags:	Unread

From:	Jeanne Redding (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:54:41
Priority:	Normal
Type:	Note

Jeanne Redding

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Jeanne Redding

Sender:	Jeanne Redding (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:48:51
Delivered Date:	2020/03/20 20:54:41
Message Flags:	Unread

From:	Heidi Adame (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:59:02
Priority:	Normal
Type:	Note

Heidi Adame

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Heidi Adame

Sender:	Heidi Adame (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:58:53
Delivered Date:	2020/03/20 20:59:02
Message Flags:	Unread

From:	Jamie Benjamin (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:58:59
Priority:	Normal
Type:	Note

Jamie Benjamin

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Jamie Benjamin

Sender:	Jamie Benjamin (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:58:53
Delivered Date:	2020/03/20 20:58:59
Message Flags:	Unread

From:	Benjamin Price (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 20:58:57
Priority:	Normal
Type:	Note

Benjamin Price

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Benjamin Price

Sender:	Benjamin Price (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 20:58:53
Delivered Date:	2020/03/20 20:58:57
Message Flags:	Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D145EFC9C35C4865ACA6E9D47786B204-HARRISON, B>
To:	Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	Fwd: New O2MAX BIO Mask
Date:	2020/03/20 21:04:38
Priority:	Normal
Type:	Note

Brian Harrison
Chief of Staff
U.S. Department of Health and Human Services
202.690.7000
brian.harrison@hhs.gov

Begin forwarded message:

From: Donald Smith <(b)(6)>
Date: March 20, 2020 at 7:26:06 PM EDT
To: "Redfield, Robert R. (CDC/OD)" <(b)(6)> "Redd, Stephen (CDC/DDPHSIS/OD)" <(b)(6)> "Yeskey, Kevin (OS/ASPR/IO)" <Kevin.Yeskey@hhs.gov>, "Lee, Barbara D (OS/ASA/PSC/FMP)" <Barbara.Lee@psc.hhs.gov>, "nicole.lurie@hhs.gov" <nicole.lurie@hhs.gov>, "Korch, George (OS/ASPR/IO)" <George.Korch@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Kendall, Damaris (HHS/OS)" <Damaris.Kendall@HHS.GOV>, "Morse, Trent (HHS/IOS)" <Trent.Morse@hhs.gov>
Cc: "Tignor, Beth (HHS/IOS)" <Beth.Tignor@hhs.gov>, "Agnew, Ann (HHS/IOS)" <Ann.Agnew@hhs.gov>, "Robinson, Wilma (HHS/IOS)" <Wilma.Robinson@hhs.gov>, "Bornstein, Josh (CDC/OCOO/OSSAM)" <(b)(6)> "Romanoff, Lovisa C. (CDC/DDPHSIS/CPR/OD)" <(b)(6)> <(b)(6)> <(b)(6)> "Butler, Jay C. (CDC/DDID/OD)" <(b)(6)> "Kuhnert-Tallman, Wendi (CDC/DDID/OD)" <(b)(6)> "Frank, Mark (CDC/DDPHSIS/CPR/DEO)" <(b)(6)> "Howard, John (CDC/NIOSH/OD)" <(b)(6)> "Kitt, Margaret (CDC/NIOSH/OD)" <(b)(6)>
Subject: New O2MAX BIO Mask

Hello,

We previously have emailed you about our novel oxygen face mask the, O2MAX. In regards to this, Sharp Medical Products, LLC has urgently developed what we believe may be the first truly

biological protective simple oxygen mask based on our O2MAX design that has elegantly combined two major functions – medical staff protection and an oxygen supply for ill patients. The expeditious development of this mask was driven by COVID-19; but this mask will be applicable to patients with any respiratory disease.

With respect to sick patients with respiratory infections (such as COVID-19); many, if not most of these, will be on supplemental oxygen from the EMS arena to the hospital through a simple oxygen mask or nasal cannula. Unfortunately, neither of these devices delivers efficient oxygen or stops the patient from spewing infectious materials (i.e., COVID19 virus) constantly through every one of their exhaled breaths; contaminating the air as well as the surrounding surfaces (ambulance, helicopter, bed, tables etc.). Obviously this creates a dangerous environment for medical personal and families requiring expensive biological containment suits and apprehension. With our mask, not only will the patient receive supplemental oxygen but in addition, we believe, the biological filter system will keep a majority of the infectious materials from leaving the mask – potentially making it much safer for the staff and possibly reducing the need for full containment suits.

Our biological oxygen mask is built using the PVC shell of our revolutionary simple oxygen mask (O2MAX commercially ready) which delivers 50% more oxygen than the market leading face masks; reducing the amount of oxygen required to achieve the same effect; for example, our mask at 5L of oxygen flow per minute results in the same oxygen levels as a standard mask at 10L. This PVC shell is then converted to a biological mask by adding viral level filter material to the air outlets as well as the edges of the mask using a specially designed gasket. The goal is for the exhaled breath to be filtered as much as possible at these two critical areas.

We have also developed a non oxygen supplying mask based on the same design that can be used as PPE for what we believe may be for an extended amount of time vs a disposable paper mask.

The significant outbreak of the COVID-19 virus is taxing the entire healthcare system. We are attempting to do our part as rapidly as possible; due to the complex issues with a rapid spin up of production and raw materials we do not yet have a delivery date – but we can promise we are doing everything we can to bring this to market rapidly. Due to the rapidly evolving nature of this world wide problem, limited time and resources we suggest the following call to action if you are interested in this mask:

1. Provide us with a \$1,500,000 grant to have the O2MAX BIO mask produced and in the hands of those needing it ASAP
2. Use the Defense Production Act to direct industry to prioritize the manufacture and distribution of the O2MAX BIO Mask

Please let me know if there is anything further I can assist with or if you know of someone/agency that you could direct us to further the process along. We request/need an expedited process/path forward to get this into the hands of healthcare personnel immediately.

Best regards,

Don

Donald Smith
Director of Corporate, Government & Military Affairs
Sharp Medical Products, LLC
don.smith@sharpmedicalproducts.com
503-730-0253

Sender:	Harrison, Brian (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D145EFC9C35C4865ACA6E9D47786B204-HARRISON, B>
Recipient:	Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/03/20 21:04:38

From:	Jordan Baum (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:16:04
Priority:	Normal
Type:	Note

Jordan Baum

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Jordan Baum

Sender:	Jordan Baum (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:08:55
Delivered Date:	2020/03/20 21:16:04
Message Flags:	Unread

From:	Erin Mccoy (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:14:51
Priority:	Normal
Type:	Note

Erin Mccoy

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Erin Mccoy

Sender:	Erin Mccoy (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:08:55
Delivered Date:	2020/03/20 21:14:51
Message Flags:	Unread

From:	Kathryn Renninger <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:13:29
Priority:	Normal
Type:	Note

Kathryn Renninger

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Kathryn Renninger

Sender:	Kathryn Renninger <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:08:55
Delivered Date:	2020/03/20 21:13:29
Message Flags:	Unread

From:	Daniel Lambert <dan@pathologywatch.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:22:04
Priority:	Normal
Type:	Note

Daniel Lambert
327 S 700 E #2
Salt Lake City, UT 84102

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Daniel Lambert

Sender:	Daniel Lambert <dan@pathologywatch.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:18:56
Delivered Date:	2020/03/20 21:22:04
Message Flags:	Unread

From:	Chandra S <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:22:37
Priority:	Normal
Type:	Note

Chandra S

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Chandra S

Sender:	Chandra S <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:18:57
Delivered Date:	2020/03/20 21:22:37
Message Flags:	Unread

From:	Mark Frushone (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:29:03
Priority:	Normal
Type:	Note

Mark Frushone

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Mark Frushone

Sender:	Mark Frushone (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:28:58
Delivered Date:	2020/03/20 21:29:03
Message Flags:	Unread

From:	Ann Cline (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:29:03
Priority:	Normal
Type:	Note

Ann Cline

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Ann Cline

Sender:	Ann Cline (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:28:58
Delivered Date:	2020/03/20 21:29:03
Message Flags:	Unread

From:	Jennifer Albers <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:29:03
Priority:	Normal
Type:	Note

Jennifer Albers
(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Jennifer Albers

Sender:	Jennifer Albers (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:28:58
Delivered Date:	2020/03/20 21:29:03
Message Flags:	Unread

From:	Carol Prokop <cprokop@arcpointlabs.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:29:05
Priority:	Normal
Type:	Note

Carol Prokop
25319 Lockspur Drive
Richmond, TX 77406

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Carol Prokop

Sender:	Carol Prokop <cprokop@arcpointlabs.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:28:58
Delivered Date:	2020/03/20 21:29:05
Message Flags:	Unread

From:	Fritz JeanPierre (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:29:04
Priority:	Normal
Type:	Note

Fritz JeanPierre

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Fritz JeanPierre

Sender:	Fritz JeanPierre (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:28:59
Delivered Date:	2020/03/20 21:29:04
Message Flags:	Unread

From:	Sweta Thakkar <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:29:09
Priority:	Normal
Type:	Note

Sweta Thakkar

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Sweta Thakkar

Sender:	Sweta Thakkar <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:28:59
Delivered Date:	2020/03/20 21:29:09
Message Flags:	Unread

From:	Jasmine Sekyere (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:39:09
Priority:	Normal
Type:	Note

Jasmine Sekyere

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Jasmine Sekyere

Sender:	Jasmine Sekyere (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:38:59
Delivered Date:	2020/03/20 21:39:09
Message Flags:	Unread

From:	Lori Proctor MD (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:39:06
Priority:	Normal
Type:	Note

Lori Proctor MD

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Lori Proctor MD

Sender:	Lori Proctor MD (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:38:59
Delivered Date:	2020/03/20 21:39:06
Message Flags:	Unread

From:	Salvatore Priore (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:39:12
Priority:	Normal
Type:	Note

Salvatore Priore

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Salvatore Priore

Sender:	Salvatore Priore (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:39:00
Delivered Date:	2020/03/20 21:39:12
Message Flags:	Unread

From:	Debbie Wollenberg (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:49:19
Priority:	Normal
Type:	Note

Debbie Wollenberg

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Debbie Wollenberg

Sender:	Debbie Wollenberg (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:49:01
Delivered Date:	2020/03/20 21:49:19
Message Flags:	Unread

From:	Emily Booker (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:49:13
Priority:	Normal
Type:	Note

Emily Booker

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Emily Booker

Sender:	Emily Booker (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:49:01
Delivered Date:	2020/03/20 21:49:13
Message Flags:	Unread

From:	Aimee Sacks (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:00:50
Priority:	Normal
Type:	Note

Aimee Sacks

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Aimee Sacks

Sender:	Aimee Sacks (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:59:02
Delivered Date:	2020/03/20 22:00:50
Message Flags:	Unread

From:	Sandra Johnson <00sandra1@frontier.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:00:27
Priority:	Normal
Type:	Note

Sandra Johnson

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Sandra Johnson

Sender:	Sandra Johnson <00sandra1@frontier.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:59:02
Delivered Date:	2020/03/20 22:00:27
Message Flags:	Unread

From:	Paul Kuznik <Pkuznik@immco.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:00:24
Priority:	Normal
Type:	Note

Paul Kuznik

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Paul Kuznik

Sender:	Paul Kuznik <Pkuznik@immco.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:59:02
Delivered Date:	2020/03/20 22:00:24
Message Flags:	Unread

From:	Mary Jablonski <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 21:59:15
Priority:	Normal
Type:	Note

Mary Jablonski

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Mary Jablonski

Sender:	Mary Jablonski <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 21:59:02
Delivered Date:	2020/03/20 21:59:15
Message Flags:	Unread

From:	Kaitlyne Johnson (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:10:23
Priority:	Normal
Type:	Note

Kaitlyne Johnson

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kaitlyne Johnson

Sender:	Kaitlyne Johnson (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:09:03
Delivered Date:	2020/03/20 22:10:23
Message Flags:	Unread

From:	Maria del Carmen Amador <mcamador@elp.rr.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:10:22
Priority:	Normal
Type:	Note

Maria del Carmen Amador

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Maria del Carmen Amador

Sender:	Maria del Carmen Amador <mcamador@elp.rr.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:09:03
Delivered Date:	2020/03/20 22:10:22
Message Flags:	Unread

From:	LUISA VELEZ <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:10:24
Priority:	Normal
Type:	Note

LUISA VELEZ

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
LUISA VELEZ

Sender:	LUISA VELEZ <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:09:04
Delivered Date:	2020/03/20 22:10:24
Message Flags:	Unread

From:	Erika Rush (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:29:12
Priority:	Normal
Type:	Note

Erika Rush

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Erika Rush

Sender:	Erika Rush (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:29:07
Delivered Date:	2020/03/20 22:29:12
Message Flags:	Unread

From:	Tracey Gardner (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:43:45
Priority:	Normal
Type:	Note

Tracey Gardner

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Tracey Gardner

Sender:	Tracey Gardner (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:39:07
Delivered Date:	2020/03/20 22:43:45
Message Flags:	Unread

From:	Li Liu (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:43:32
Priority:	Normal
Type:	Note

Li Liu

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Li Liu

Sender:	Li Liu (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:39:07
Delivered Date:	2020/03/20 22:43:32
Message Flags:	Unread

From:	Robert Trelease <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:50:20
Priority:	Normal
Type:	Note

Robert Trelease
Department of Pathology And Laboratory Medicine
Los Angeles, CA 90095

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Robert Trelease

Sender:	Robert Trelease <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:49:09
Delivered Date:	2020/03/20 22:50:20
Message Flags:	Unread

From:	Marlene Dargelo (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:49:13
Priority:	Normal
Type:	Note

Marlene Dargelo

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Marlene Dargelo

Sender:	Marlene Dargelo (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:49:09
Delivered Date:	2020/03/20 22:49:13
Message Flags:	Unread

From:	Wendy Weitzel (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:50:45
Priority:	Normal
Type:	Note

Wendy Weitzel

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

I am not affected directly by these decisions since I specialize in Core Laboratory and Reference Lab testing. I am one of the technologists handling the COVID-19 specimens to be sent to Quest and Labcorp. 2020 is my 35th year of being a Medical Technologist at Lancaster General Hospital, Lancaster, PA. My career started with all the uncertainty of AIDS and likely COVID-19 will not be the last scary illness to affect Americans. Please help the laboratory staff be able to work remotely. Thank you.

Sincerely,
Wendy Weitzel, MT(ASCP)

Sender:	Wendy Weitzel (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:49:10
Delivered Date:	2020/03/20 22:50:45
Message Flags:	Unread

From:	Bethany Tierno (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 22:59:17
Priority:	Normal
Type:	Note

Bethany Tierno

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Bethany Tierno, MD

Sender:	Bethany Tierno (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 22:59:11
Delivered Date:	2020/03/20 22:59:17
Message Flags:	Unread

From:	Michelle Guarino (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 23:11:17
Priority:	Normal
Type:	Note

Michelle Guarino

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Michelle Guarino

Sender:	Michelle Guarino (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 23:09:12
Delivered Date:	2020/03/20 23:11:17
Message Flags:	Unread

From:	Mike Igelman <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 23:11:12
Priority:	Normal
Type:	Note

Mike Igelman

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Mike Igelman

Sender:	Mike Igelman <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 23:09:12
Delivered Date:	2020/03/20 23:11:12
Message Flags:	Unread

From:	Yvette Gonzalez <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 23:19:17
Priority:	Normal
Type:	Note

Yvette Gonzalez

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Yvette Gonzalez

Sender:	Yvette Gonzalez <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 23:19:13
Delivered Date:	2020/03/20 23:19:17
Message Flags:	Unread

From:	Melanie Brown (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 23:19:19
Priority:	Normal
Type:	Note

Melanie Brown

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Melanie Brown

Sender:	Melanie Brown (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 23:19:13
Delivered Date:	2020/03/20 23:19:19
Message Flags:	Unread

From:	Kathy Kwong (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 23:19:19
Priority:	Normal
Type:	Note

Kathy Kwong

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kathy Kwong

Sender:	Kathy Kwong (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 23:19:13
Delivered Date:	2020/03/20 23:19:19
Message Flags:	Unread

From:	Simon Arkell <simon@deeplens.ai>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 23:19:22
Priority:	Normal
Type:	Note

Simon Arkell

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Simon Arkell

Sender:	Simon Arkell <simon@deeplens.ai>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 23:19:13
Delivered Date:	2020/03/20 23:19:22
Message Flags:	Unread

From:	Lindy Lemley <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/20 23:19:24
Priority:	Normal
Type:	Note

Lindy Lemley

(b)(6)

March 20, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Lindy Lemley

Sender:	Lindy Lemley <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/20 23:19:13
Delivered Date:	2020/03/20 23:19:24
Message Flags:	Unread

From:	Dana Tomasello <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 00:16:09
Priority:	Normal
Type:	Note

Dana Tomasello

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Dana Tomasello

Sender:	Dana Tomasello <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 00:14:33
Delivered Date:	2020/03/21 00:16:09
Message Flags:	Unread

From:	Megan Flores (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 00:24:40
Priority:	Normal
Type:	Note

Megan Flores

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Megan Flores

Sender:	Megan Flores (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 00:24:35
Delivered Date:	2020/03/21 00:24:40
Message Flags:	Unread

From:	Silvia Bunting <Silvia.bunting@moffitt.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 00:24:42
Priority:	Normal
Type:	Note

Silvia Bunting

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Silvia Bunting

Sender:	Silvia Bunting <Silvia.bunting@moffitt.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 00:24:36
Delivered Date:	2020/03/21 00:24:42
Message Flags:	Unread

From:	Julio Diaz-Perez <julio.diazperez@jhsmiami.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 00:36:12
Priority:	Normal
Type:	Note

Julio Diaz-Perez

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Julio Diaz-Perez

Sender:	Julio Diaz-Perez <julio.diazperez@jhsmiami.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 00:34:37
Delivered Date:	2020/03/21 00:36:12
Message Flags:	Unread

From:	Alexandra Figueroa (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 00:36:13
Priority:	Normal
Type:	Note

Alexandra Figueroa

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Alexandra Figueroa

Sender:	Alexandra Figueroa (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 00:34:37
Delivered Date:	2020/03/21 00:36:13
Message Flags:	Unread

From:	Dorothy Dincecco (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 00:55:01
Priority:	Normal
Type:	Note

Dorothy Dincecco

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Dorothy Dincecco

Sender:	Dorothy Dincecco (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 00:54:38
Delivered Date:	2020/03/21 00:55:01
Message Flags:	Unread

From:	Adel Assaad (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:04:45
Priority:	Normal
Type:	Note

Adel Assaad

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

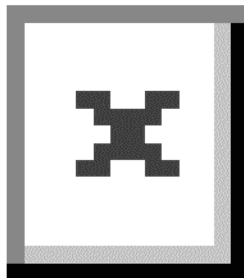
The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

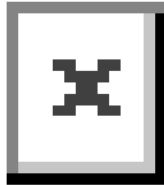
Sincerely,
Adel Assaad

Sender:	Adel Assaad (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:04:39
Delivered Date:	2020/03/21 01:04:45
Message Flags:	Unread

From:	Project Patient Care <pmerryweather@projectpatientcare.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Special COVID-19 Edition #2
Date:	2020/03/21 01:10:16
Priority:	Normal
Type:	Note



COVID-19 Special Edition # 2 - March 20, 2020



Greetings - we hope this finds you, your family, and loved ones in good health.

In Illinois, starting March 21 at 5:00 p.m. central time, we are all under a Stay at Home Order through April 7. Before we were under a Social Distancing Order that allowed people to go about their daily activities while taking extra health and safety precautions. The Stay at Home order requires people to remain in their homes unless they have an essential job or are doing an essential task like going to the grocery store or walking a pet. In Illinois, please check the [Illinois Frequently Asked Questions](#) on Stay at Home Order.

However, we know that each state is different, but we do have some common issues that are confronting all consumers, patients, nursing home residents, healthcare providers, and public health professionals.

Our next Edition will be out on Monday and will cover COVID-19 Testing and TeleHealth, which is turning out to be a lifeline for many people during this COVID-19 pandemic.

Need for Personal Protective Equipment (PPE) - Needed Now

Hospitals across the United States are in great need for PPE, especially the N95 Masks. In addition to hospitals using N95 masks, construction companies and dental offices often times use and have a stock of N95 masks.

Unfortunately it is not a matter of purchasing the N95 masks as all hospitals have backorders in with manufacturers; there is not just enough supply to meet the growing need.

Similar to other hospital associations, the Illinois Hospital Association is making a plea to all residents and those that have connections to construction companies and closed dental offices, to bring the N95 masks to your local hospital. " We anticipate that the number of cases

will increase dramatically in the coming days and weeks, exhausting all the PPE at hospitals, including gowns, gloves, eye shields and, especially, medical masks..... PPE is critical to protecting our frontline healthcare workforce from infection when testing and treating patients for COVID-19, keeping our dedicated physicians, nurses, technicians and others in our hospitals where they are needed most." For more info, click [Here](#)

Please reach out to your local construction companies and dental offices to make them aware of the need of their local hospital.

Long Term Care Facility (Nursing Home)/Congregate Care Assessment of COVID-19 Preparedness - Needed Now

As noted in our COVID-19 Newsletter Edition #1, nursing homes have many challenges in caring for residents that are often time in close quarters. While there are specific guidelines that have been given to nursing home administrators and staff, there have been gaps in consistent implementation of infection control and prevention. While Seattle had a high profile case, Illinois has also had a high impact COVID-19 break in infection prevention and control as have other nursing homes throughout the U.S.

The Illinois Department of Public Health is in need of focusing their staff resources to the nursing homes and congregate care (assisted living facilities) that are in need of education, training, and supplies. In particular, they are requesting that anyone that has a loved one in a nursing home, works at a nursing home, or is familiar with their local nursing home - please urge them to complete and submit the Survey to IDPH no later than March 27. Based upon responses to the survey, IDPH staff will assist the nursing homes most at risk to having a COVID-19 cluster outbreak due to not having the systems or PPE in place.

IDPH's survey , similar to many states, covers the following COVID-19 related issues:

- • Visitor restrictions
- • Education, monitoring, and screening of Healthcare Personnel (HCP)
- • Education, monitoring, and screening of Residents
- • Availability of Personal Protective Equipment (PPE) and other supplies
- • Infection Prevention Practices:
 - • Hand hygiene
 - • Use of PPE
 - • Cleaning and disinfection of environmental surfaces and resident care equipment





We Enjoy Hearing From You!

We are always happy to hear from you - please feel free to contact us at any time. During the COVID-19 pandemic, our staff will be working from home.

Contact Pat Merryweather-Arges:

Telephone: 630-202-5579

E-mail: pmerryweather@projectpatientcare.org

Thank you!

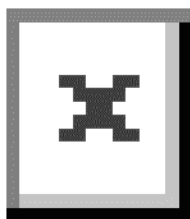
Project Patient Care | 321 N. Clark Street, Suite 500, Chicago, IL 60654

[Unsubscribe Alex.Azar@HHS.GOV](#)

[About Constant Contact](#)

Sent by

pmerryweather@projectpatientcare.org
in collaboration with



Trusted Email from
Constant Contact - Try it
FREE today.

Try email marketing for free
today!

Sender:	Project Patient Care <pmerryweather@projectpatientcare.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:10:09
Delivered Date:	2020/03/21 01:10:16
Message Flags:	Unread

From:	Janet Seyfert-Peck (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:14:50
Priority:	Normal
Type:	Note

Janet Seyfert-Peck

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Janet Seyfert-Peck

Sender:	Janet Seyfert-Peck (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:14:40
Delivered Date:	2020/03/21 01:14:50
Message Flags:	Unread

From:	Deborah Regidor (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:14:57
Priority:	Normal
Type:	Note

Deborah Regidor

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Deborah Regidor

Sender:	Deborah Regidor (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:14:40
Delivered Date:	2020/03/21 01:14:57
Message Flags:	Unread

From:	Gracie Jiang (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:24:46
Priority:	Normal
Type:	Note

Gracie Jiang

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Gracie Jiang

Sender:	Gracie Jiang (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:24:40
Delivered Date:	2020/03/21 01:24:46
Message Flags:	Unread

From:	Narjes Mousavi (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:34:46
Priority:	Normal
Type:	Note

Narjes Mousavi

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Narjes Mousavi

Sender:	Narjes Mousavi (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:34:41
Delivered Date:	2020/03/21 01:34:46
Message Flags:	Unread

From:	Ruth Cheng (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:35:46
Priority:	Normal
Type:	Note

Ruth Cheng

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Ruth Cheng

Sender:	Ruth Cheng (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:34:41
Delivered Date:	2020/03/21 01:35:46
Message Flags:	Unread

From:	Mary Kitabjian <Mary@kitabjian.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:35:46
Priority:	Normal
Type:	Note

Mary Kitabjian

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Mary Kitabjian

Sender:	Mary Kitabjian <Mary@kitabjian.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:34:41
Delivered Date:	2020/03/21 01:35:46
Message Flags:	Unread

From:	Chanthy Som (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:44:47
Priority:	Normal
Type:	Note

Chanthy Som

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Chanthy Som

Sender:	Chanthy Som (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:44:42
Delivered Date:	2020/03/21 01:44:47
Message Flags:	Unread

From:	Flor Madera (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 01:54:46
Priority:	Normal
Type:	Note

Flor Madera

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Flor Madera

Sender:	Flor Madera (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 01:54:42
Delivered Date:	2020/03/21 01:54:46
Message Flags:	Unread

From:	Tamara Holland <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 02:24:49
Priority:	Normal
Type:	Note

Tamara Holland

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Tamara Holland

Sender:	Tamara Holland <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 02:24:45
Delivered Date:	2020/03/21 02:24:49
Message Flags:	Unread

From:	Loretta Sproul (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 02:44:50
Priority:	Normal
Type:	Note

Loretta Sproul

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Loretta Sproul, MT(ASCP)

Sender:	Loretta Sproul (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 02:44:46
Delivered Date:	2020/03/21 02:44:50
Message Flags:	Unread

From:	Gail Gainen (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 02:54:58
Priority:	Normal
Type:	Note

Gail Gainen

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Gail Gainen

Sender:	Gail Gainen (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 02:54:47
Delivered Date:	2020/03/21 02:54:58
Message Flags:	Unread

From:	Kim Squyars (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 03:06:54
Priority:	Normal
Type:	Note

Kim Squyars

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kim Squyars

Sender:	Kim Squyars (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 03:04:47
Delivered Date:	2020/03/21 03:06:54
Message Flags:	Unread

From:	Scott Rimbaugh (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 03:59:50
Priority:	Normal
Type:	Note

Scott Rimbaugh

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Scott Rimbaugh

Sender:	Scott Rimbaugh (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 03:59:38
Delivered Date:	2020/03/21 03:59:50
Message Flags:	Unread

From:	Roberta Hatch <roberta@sanbrunocable.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 04:11:48
Priority:	Normal
Type:	Note

Roberta Hatch

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Roberta Hatch

Sender:	Roberta Hatch <roberta@sanbrunocable.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 04:09:39
Delivered Date:	2020/03/21 04:11:48
Message Flags:	Unread

From:	Francis Akpan (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 04:19:44
Priority:	Normal
Type:	Note

Francis Akpan

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Francis Akpan

Sender:	Francis Akpan (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 04:19:40
Delivered Date:	2020/03/21 04:19:44
Message Flags:	Unread

From:	Aisha Clinton <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 04:39:47
Priority:	Normal
Type:	Note

Aisha Clinton

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Aisha Clinton

Sender:	Aisha Clinton <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 04:39:41
Delivered Date:	2020/03/21 04:39:47
Message Flags:	Unread

From:	Debra Jacobsen (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 05:29:51
Priority:	Normal
Type:	Note

Debra Jacobsen

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Debra Jacobsen

Sender:	Debra Jacobsen (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 05:29:46
Delivered Date:	2020/03/21 05:29:51
Message Flags:	Unread

From:	Heather Wiseman <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 05:49:56
Priority:	Normal
Type:	Note

Heather Wiseman

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Heather Wiseman

Sender:	Heather Wiseman <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 05:49:47
Delivered Date:	2020/03/21 05:49:56
Message Flags:	Unread

From:	JAMA Network <updates@jamanetwork.org>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.up (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	Health Policy Weekly Highlights from the JAMA Network
Date:	2020/03/21 06:45:52
Priority:	Normal
Type:	Note

Trouble viewing this email? [Read it Online](#)

[.Weekly Highlights from The JAMA Network - Selected journal articles from across the 11 JAMA Network clinical research journals](#)

Advertisement Advertisement

Weekly Highlights: Health Policy



[facebook icon](#)



[linked in icon](#)



[youtube icon](#)



[twitter icon](#)



[pinterest icon](#)

These **Health Policy** articles you may have missed were published this past week across the JAMA Network. Click below to read them for FREE.

RESEARCH

JAMA

**Return on Investment From
Co-locating Tax Assistance for Low-Income Persons at
Clinical Sites**

Shinelle Black; Sarah Sisco, MPH, MSSW; Tatiana Williams, MBA; et al

JAMA Network Open

**Association of Mental Health
Disorders With Health Care Spending in the Medicare
Population**

Jose F. Figueroa, MD, MPH; Jessica Phelan, MSc; E. John Orav, PhD; et al

JAMA Network Open

**Assessment of Differences in
Inpatient Rehabilitation Services for Length of Stay and Health
Outcomes Between US Medicare Advantage and Traditional
Medicare Beneficiaries**

Ying Cao, PhD; Jing Nie, PhD; Sue Ann Sisto, PT, PhD; et al

JAMA Network Open

**Association of Declines in
End-of-Life Health Care Costs With Fee-for-Service Enrollee
Per Capita Expenditures**

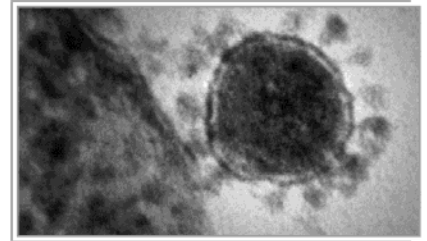
William B. Weeks, MD, PhD, MBA; Stacey Y. Cao, MHS; Chris M. Lester, PhD; et al

2019 CORONAVIRUS

JAMA Network Open

Association of a Lay Health Worker Intervention With Symptom Burden, Survival, Health Care Use, and Total Costs Among Medicare Enrollees With Cancer

Manali I. Patel, MD, MPH, MS; David Ramirez, MD; Richy Agajanian, MD; et al



OPINION

JAMA

Securing the Safety Net and Protecting Public Health During a Pandemic: Medicaid's Response to COVID-19

Chethan Bachireddy, MD, MSc; Christopher Chen, MD, MBA; Mohammad Dar, MD

[JAMA Network's COVID-19 Resource Center](#)

JAMA

Presidential Powers and Response to COVID-19

Lawrence O. Gostin, JD; James G. Hodge Jr, JD, LL.M; Lindsay F. Wiley, JD, MPH

JAMA

Shortcomings in the US Pharmaceutical Supply Chain: Potential Risks Associated With International Manufacturing and Trade-Related Tariffs

JOB LISTINGS ON JAMA

Richard L. Oehler, MD; Sandra G. Gompf, MD

CAREER CENTER®

JAMA

**Managing COVID-19 in Low-
and Middle-Income Countries**

Joost Hopman, MD, PhD, DTMH; Benedetta Allegranzi, MD, DTMH; Shaheen Mehtar, MBBS, MD (Lon)

**Dean for Medical
Education**

Washington D.C.

JAMA

**From Containment to
Mitigation of COVID-19 in the US**

Stephen M. Parodi, MD; Vincent X. Liu, MD, MSc

**Vice President for Health
Affairs and Dean of the
Sanford School of
Medicine**

Vermillion, South Dakota

AUDIO

Clinical Review Audio

**COVID-19 in Seattle: Clinical
Features and Managing the Outbreak**

**Primary Care Physician -
St. Louis**

Saint Louis, Missouri

Clinical Review Audio

Primary Care Physician -

The Effect of the COVID-19

Pandemic on Clinic Operations

Conversations with Dr Bauchner

Coronavirus Testing

Conversations with Dr Bauchner

Coronavirus in Italy—Report

From the Front Lines

Cleveland

Cleveland, Ohio, United States

Osteopathic Principles and Practice Clinical Faculty (Greensburg, PA)

Greensburg, Pennsylvania

[See more](#)

[at JAMA Career Center](#)

VIDEO

JAMA Livestream

Coronavirus Update with

Anthony Fauci, MD – March 18, 2020

Anthony Fauci, MD, talks with JAMA Editor Howard

Bauchner, MD

JAMA Livestream

Coronavirus (COVID-19)

Mitigation: Preparing Hospitals and Health Systems

Q&A with Kaiser Permanente EVP Stephen M.

Parodi

JAMA Livestream

Coronavirus (COVID-19)

Testing

An interview with Jay C. Butler, MD, from the CDC

TRENDING NOW ON *JAMA HEALTH FORUM*

Coronavirus
Outbreak—an Evolving Global Health Emergency

Love of the UK's
National Health Service—and Its Lessons for Health Policy

Changes in Cancer
Staging and Timely Treatment After Medicaid Expansion

Putting Health at the
Center of Care Management

Challenges in
Navigating a New Marijuana Retail Environment



JAMA Network™

JAMA Network signature

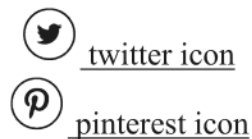
Thank you for subscribing to JAMA Network email alerts. This message was sent to **Robert.Kadlec@hhs.gov** by updates@jamanetwork.org.

To update your contact information, change your email preferences, or unsubscribe, [click here](#).

To ensure you always receive JAMA Network emails, add the email address updates@jamanetwork.org to your address book.

To unsubscribe by mail, contact:

JAMA Network
AMA Plaza
330 N Wabash Ave
Chicago, IL 60611
Or call (800) 621-8335.



©2020 American Medical Association. All rights reserved.

CALL FOR PAPERS

JAMA
Network | Open™

JAMA Network Advertisement Advertisement

Sender:	JAMA Network <updates@jamanetwork.org>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/03/21 06:45:15
Delivered Date:	2020/03/21 06:45:52
Message Flags:	Unread

From:	Agnes Gregory (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 06:49:57
Priority:	Normal
Type:	Note

Agnes Gregory

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Agnes Gregory

Sender:	Agnes Gregory (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 06:49:52
Delivered Date:	2020/03/21 06:49:57
Message Flags:	Unread

From:	Hannah Anthony (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 06:49:58
Priority:	Normal
Type:	Note

Hannah Anthony

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

I am an inpatient phlebotomist. I have very close contact with patients throughout the hospital. Especially with the severe shortages we are seeing on personal protective equipment like masks and gowns, having the ability to quickly screen patients for covid19 is vitally important. We are able to test very few patients at this time, and the longer it takes for results, the more chances there are for healthcare workers to be exposed, spread the virus to other patients, their families and possibly become unable to work. We do not have the option to distance ourselves like so many who are sheltering in their homes. Please help us by giving us the tools that can get us through these dangerous times. Thank you for your consideration.

Sincerely,
Hannah Anthony

Sender:	Hannah Anthony (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 06:49:52
Delivered Date:	2020/03/21 06:49:58
Message Flags:	Unread

From:	Denise Muiee (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/21 07:00:21
Priority:	Normal
Type:	Note

Denise Muiee

(b)(6)

March 21, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Denise Muiee

Sender:	Denise Muiee (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/21 06:59:53
Delivered Date:	2020/03/21 07:00:21
Message Flags:	Unread

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 21Mar20
Date:	2020/03/21 07:09:37
Priority:	Normal
Type:	Note

UNCLASSIFIED // FOR OFFICIAL USE ONLY

HHS Executive Summary: Saturday, 21Mar20

1. HHS

Today's Noteworthy Topics:

COVID-19 (Novel Coronavirus)

As of 20Mar20, 1700ET, the CDC confirmed and presumptive positive U.S. cases of COVID-19 have reached 14,086 across 50 states and D.C. Guam, PR and USVI; Deaths: 199; Combined CDC and WHO reported global cases: 209,839; global deaths: 8771; Countries with cases: 172. The FEMA NRCC is operating at Level 1, in a unified effort with the HHS SOC. FEMA and HHS Regions have integrated to joint operations and continue to work requirements in support of state, tribal, and territorial requests. A joint campaign plan was developed to focus the efforts of the multiple task forces established to facilitate the overall COVID-19 response. Primary efforts are on providing resources to the states in greatest need while researching capacity across the private sector. Multiple jurisdictions, including California and New York, have announced "Stay at Home" orders.

Daily Operational Schedule:

0830 – FEMA Daily Operations Briefing
 1100 – Grand Princess Call
 1230 – Joint HHS/FEMA Interagency VTC
 1300 – IMD Sync Call for COVID-19 and Repatriation
 1400 – COVID-19 Resource Coordination Call

Public Health Emergency of National Significance:

Puerto Rico (Earthquake): 08Jan20
 Opioid Crisis, Nationwide: 24Jan20
 Novel Coronavirus (COVID-19): 31Jan20

HHS Response Status Summary:

HHS SOC: Level I (Full Activation)
 CDC EOC: Level III (Polio/Ebola)
 CDC EOC: COVID-19 (Agency-Wide Response)
 FDA EOC: Level II (Vape Product Response, COVID-19)

Emergency Support Function (ESF) Activation:

ESF – 8: Activated
ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 30Jun20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20).

HHS Deployments: (Total = 1,462)

ASPR: 1,196 – (9) Earthquake Puerto Rico, (1,173) COVID-19, (5) Irma/Maria Recovery, (3) Irma, (2) FY Funded Training Q1, (2) FY Non-Funded Training Q1, (1) California Wildfires, (1) California Wildfires Recovery

CDC: 266 – (234) COVID-19, (8) Polio, (24) Ebola

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 9 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR

Active Situations (7):

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- • * Novel Coronavirus (COVID-19)
- • * Bravo Response
- • * Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: Monitoring

NRCC: Level I

National IMATs: Red – Fully Mission Capable; Blue – Fully Mission Capable; Gold – Fully Mission Capable

Regional IMATs: Region II, NY; Region IV-2, TN; Region IX-2, RRCC; Region X, RRCC

Significant National Weather:

A weather system will bring the potential for strong thunderstorms, heavy rainfall, and localized flooding from the Texas South Plains to the lower Mississippi Valley on Saturday. A coastal storm will develop off the Mid Atlantic coast and intensify early next week. Rain and gusty winds will be common for the I-95 corridor. Interior sections including New England may see wintry precipitation.

3. OPDIV/STAFFDIV Overnight Reports:

CDC:

- • * COVID-19 – 161 Locations (including countries, territories, and areas) – Update
- • * Dengue – Marshall Islands – Update
- • * Measles (Rubeola) – Democratic Republic of the Congo – Update
- • * Polio (Wild Type) – Pakistan – Update
- • * Polio (Vaccine-derived) – Angola – Update
- • * Polio (Vaccine-derived) – Chad – Update
- • * Polio (Vaccine-derived) – Côte d'Ivoire – Update
- • * Polio (Vaccine-derived) – Malaysia – Update
- • * Polio (Vaccine-derived) – Pakistan – Update
- • * Lassa Fever - Nigeria – Update

FDA:

- Adverse Events Possibly Linked to Vaping Products/Unknown/ML/Aug 2019
- Coronavirus Disease 2019 (COVID-19)/ML/2019
- *Salmonella* Braenderup/Fruit (suspect)/Dec 2019
- *E. coli* O103:H2/Produce (Suspect)/Feb 2020
- Hepatitis A Virus/Fresh Fruit (Suspect)/Jan 2020
- *Listeria monocytogenes*/Produce (Suspect)/Feb 2020

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
 Assistant Secretary for Preparedness and Response (ASPR)
 200 Independence Ave., S.W.
 Washington, D.C. 20201
 Office: (202) 619 – 7800
 Fax: 1-800-514-4256
 Email: hhs.soc@hhs.gov



cid:image001.png@01D5F637.9AFA0B50

Data enclosed in this email are subject to the Privacy Act of 1974, as amended. Contents shall not be disclosed, discussed, or shared with individuals unless they have a direct need-to-know in the performance of their official duties. Unauthorized disclosure of this information may result in civil or criminal penalties.

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

UNCLASSIFIED // FOR OFFICIAL USE ONLY

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
----------------	---

Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/03/21 07:09:25
Delivered Date:	2020/03/21 07:09:37

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS International FYSA: Novel Coronavirus, Wuhan, China (Update#3)
Date:	2020/01/15 20:46:03
Priority:	Normal
Type:	Note

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update#3)

The current situation relates to an outbreak of Novel Coronavirus in Wuhan City, Hubei Province, China. Some patients were linked to a large local seafood and animal market.

- **On 15Jan20**, Chinese health officials reported 41 confirmed infections with the new coronavirus; 6 patients had severe illness; and one had died, and 7 patients had been discharged.
- **The existing investigation results indicate that no clear evidence of human-to-human transmission has been found and the possibility of limited human-to-human transmission cannot be ruled out, but the risk of sustained human-to-human transmission is low.**
- **Environmental specimens were collected and tested in the South China Seafood Wholesale Market. As of January 14, the test results found that some samples were positive for 2019-nCoV.**
- **On January 13, Thailand reported a confirmed case of nCoV in a traveler from Wuhan City to Thailand. This is the first infection with 2019-nCoV outside of China.**
The patient is reportedly recovered but remains in isolation until testing negative for the coronavirus family by PCR and remains negative for 48 hours.
- **CDC's Division of Global Migration and Quarantine (DGMQ) continues planning for standup of traveler entry screening in San Francisco, Los Angeles and John F Kennedy airports.**
- **CDC China office met with DHS/CBP at Mission China to discuss CDC and DHS/CBP plans for enhancing screening of passengers with Wuhan travel history at three US airports that is scheduled to start this week.**

For more details, please see attached CDC SITREP for Novel Coronavirus.

The SOC will continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Brian Pittman, Watch Officer

Approved by: Henry E. Coleman Jr., Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response (ASPR)

200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
Description: Description: Description: Description: Description:
cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/15 20:45:56
Delivered Date:	2020/01/15 20:46:03

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS International FYSA: Novel Coronavirus, Wuhan, China (Update#3)
Date:	2020/01/15 20:46:03
Priority:	Normal
Type:	Note

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update#3)

The current situation relates to an outbreak of Novel Coronavirus in Wuhan City, Hubei Province, China. Some patients were linked to a large local seafood and animal market.

- **On 15Jan20**, Chinese health officials reported 41 confirmed infections with the new coronavirus; 6 patients had severe illness; and one had died, and 7 patients had been discharged.
- **The existing investigation results indicate that no clear evidence of human-to-human transmission has been found and the possibility of limited human-to-human transmission cannot be ruled out, but the risk of sustained human-to-human transmission is low.**
- **Environmental specimens were collected and tested in the South China Seafood Wholesale Market. As of January 14, the test results found that some samples were positive for 2019-nCoV.**
- **On January 13, Thailand reported a confirmed case of nCoV in a traveler from Wuhan City to Thailand. This is the first infection with 2019-nCoV outside of China.**
The patient is reportedly recovered but remains in isolation until testing negative for the coronavirus family by PCR and remains negative for 48 hours.
- **CDC's Division of Global Migration and Quarantine (DGMQ) continues planning for standup of traveler entry screening in San Francisco, Los Angeles and John F Kennedy airports.**
- **CDC China office met with DHS/CBP at Mission China to discuss CDC and DHS/CBP plans for enhancing screening of passengers with Wuhan travel history at three US airports that is scheduled to start this week.**

For more details, please see attached CDC SITREP for Novel Coronavirus.

The SOC will continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Brian Pittman, Watch Officer

Approved by: Henry E. Coleman Jr., Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response (ASPR)

200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
Description: Description: Description: Description: Description:
cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/15 20:45:56
Delivered Date:	2020/01/15 20:46:03
Message Flags:	Unread

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 16Jan20
Date:	2020/01/16 07:07:36
Priority:	Normal
Type:	Note

HHS Executive Summary: Thursday, 16Jan20

1. HHS

Today's Noteworthy Topics:

Earthquake, Puerto Rico

A 6.4-magnitude earthquake with numerous aftershocks of similar but lower magnitudes struck 8.4 miles south of Guayanilla, Puerto Rico at approximately 0345ET on 07Jan20. Power in PR is 99% restored approximately 6,800 customers, less than 1% of customers in PR, remain without power. One dialysis center in Yauco remains closed and under evaluation for structural damage and staff safety. HHS assessment team is in the process of demobilizing. Emergency Prescription Assistance Program (EPAP) implementation was completed on 14Jan20. Public Health Service (HHS) received a mission assignment for a Behavioral Health Team of four (4) stress counselors to provide support services to federal response workers.

Novel Coronavirus, Wuhan, China

On 15Jan20, Chinese health officials reported 41 confirmed infections with the new coronavirus; 6 patients had severe illness; one has died, and 7 patients had been discharged. The existing investigation indicate that no clear evidence of human-to-human transmission has been found, but cannot be ruled out; however, the risk is low. Environmental specimens were collected and tested in the South China Seafood Wholesale Market. As of 14Jan20, the test results found that some samples were positive for 2019-nCoV. On 13Jan20, Thailand reported a confirmed case of nCoV in a traveler from Wuhan City to Thailand. This is the first infection with 2019-nCoV outside of China. The patient is reportedly recovered but remains in isolation until testing negative for 48 hours. CDC's Division of Global Migration and Quarantine (DGMQ) continues planning for standup of traveler entry screening in San Francisco, Los Angeles and John F. Kennedy airports. CDC China office met with DHS/CBP at Mission China to discuss CDC and DHS/CBP plans for enhancing screening of passengers with Wuhan travel history at three U.S. airports that is scheduled to start this week.

Medical Gown Supplier Pending Recall and Impacts

On 15Jan20 SOC was notified by the HHS Critical Infrastructure Protection Division of a manufacturing quality issue likely to result in a nationwide recall of Cardinal Health level 3 surgical gowns and PreSource procedure kits containing those gowns. The FDA is currently working with Cardinal Health on the pending recall. Cardinal Health has notified its customers of the situation and has issued a voluntary product hold advising that affected products and packs containing the products should not be used. The issue is potential contamination and does not involve fit, form, or function of the gowns. The hold and recall

are likely to cause nationwide spot shortages of product. Cardinal Health's suppliers are ramping up production volume and FDA is working with Cardinal Health to identify alternative sources of product. Several health systems who rely on Cardinal Health for a majority of product have reported impacts including cancellation of elective surgeries as they remove product from rotation.

Daily Operational Schedule:

0800 – SOC IST Start Shift Brief
0830 – FEMA Daily Operations Briefing
1215 – ASPR SLT Concall
1230 – FEMA Interagency Teleconference – Puerto Rico Earthquake
1430 – AMA Briefing
1700 – SOC IST End Shift Brief

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19
Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level III (Virtual)
CDC EOC: Level III (Polio/Ebola/Lung Injury)
FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated
ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 29Feb20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 79)

ASPR: 12 – (3) Irma/Maria, (1) 2018 California Wildfires, (8) 2020 Earthquake Puerto Rico
CDC: 67 – (25) Polio, (40) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): 3426EM-PR-HHS-05: FEMA has sent, and HHS has accepted, a mission assignment to provide appropriate personnel to support FEMA disaster operations in Puerto Rico. This mission assignment provides \$37,500.00, with an estimated projected end date of 22Jan20, for a HHS PHS Behavioral Health Team, of four (4) stress counselors to provide support services to federal response workers as deemed necessary in support of disaster operations.

Active Situations (7):

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)

- □Novel Coronavirus, China
- □Bravo Response
- □Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: EW (Nights)

NRCC: ROC/Gold (Days)

National IMATs: Red – Fully Mission Capable; Blue – Deployed - PR; Gold – Deployed - PR

Regional IMATs: Region I, PR; Region II, PR; Region VIII, SD

Significant National Weather:

Freezing rain possible for portions of the TX and OK panhandles, northern AR, much of the Central Plains and southeastern SD. Heavy snow forecast for higher elevations of the Southern/Central Rockies, Sierra Nevada, and Cascade mountains. Heavy rain/thunderstorms possible for California, Pacific Northwest, and much of the Southern Plains.

3. OPDIV/STAFFDIV Overnight Reports:

CDC:

- □The Democratic Republic of the Congo – Update

FDA:

- □ *Listeria monocytogenes*/Leafy Greens (suspect)/ Dec 2019
- □ Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- □Salmonella Saintpaul (1912MLJN6-1)/Fruit (suspect)/ Dec 2019
- □ E. coli O157:H7/Leafy greens (suspect)/ Dec 2019

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response (ASPR)

200 Independence Ave., S.W.

Washington, D.C. 20201

Office: (202) 619 – 7800

Fax: (202) 619 – 8602

Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received

this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/16 07:07:25
Delivered Date:	2020/01/16 07:07:36
Message Flags:	Unread

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	(Correction) HHS Executive Summary 17Jan20
Date:	2020/01/16 07:59:08
Priority:	Normal
Type:	Note

HHS Executive Summary: Friday, 17Jan20

(Correction: See noteworthy item: Medical Gown Supplier Pending Recall and Impacts)

1. HHS

Today's Noteworthy Topics:

Earthquake, Puerto Rico

A 6.4-magnitude earthquake with numerous aftershocks of similar but lower magnitudes struck 8.4 miles south of Guayanilla, Puerto Rico at approximately 0345ET on 07Jan20. Power in PR is 99% restored approximately 6,800 customers, less than 1% of customers in PR, remain without power. One dialysis center in Yauco remains closed and under evaluation for structural damage and staff safety. HHS assessment team is in the process of demobilizing. Emergency Prescription Assistance Program (EPAP) implementation was completed on 14Jan20. Public Health Service (HHS) received a mission assignment for a Behavioral Health Team of four (4) stress counselors to provide support services to federal response workers.

Novel Coronavirus, Wuhan, China

On 15Jan20, Chinese health officials reported 41 confirmed infections with the new coronavirus; 6 patients had severe illness; one has died, and 7 patients had been discharged. The existing investigation indicate that no clear evidence of human-to-human transmission has been found, but cannot be ruled out; however, the risk is low. Environmental specimens were collected and tested in the South China Seafood Wholesale Market. As of 14Jan20, the test results found that some samples were positive for 2019-nCoV. On 13Jan20, Thailand reported a confirmed case of nCoV in a traveler from Wuhan City to Thailand. This is the first infection with 2019-nCoV outside of China. The patient is reportedly recovered but remains in isolation until testing negative for 48 hours. CDC's Division of Global Migration and Quarantine (DGMQ) continues planning for standup of traveler entry screening in San Francisco, Los Angeles and John F. Kennedy airports. CDC China office met with DHS/CBP at Mission China to discuss CDC and DHS/CBP plans for enhancing screening of passengers with Wuhan travel history at three U.S. airports that is scheduled to start this week.

Medical Gown Supplier Pending Recall and Impacts

This information may be shared with peers and partner organizations but not via publicly accessible channels.

On 15Jan20 SOC was notified by the HHS Critical Infrastructure Protection Division of a manufacturing quality issue likely to result in a nationwide recall of Cardinal Health level 3

surgical gowns and PreSource procedure kits containing those gowns. The FDA is currently working with Cardinal Health on the pending recall. Cardinal Health has notified its customers of the situation and has issued a voluntary product hold advising that affected products and packs containing the products should not be used. The issue is potential contamination and does not involve fit, form, or function of the gowns. The hold and recall are likely to cause nationwide spot shortages of product. Cardinal Health's suppliers are ramping up production volume and FDA is working with Cardinal Health to identify alternative sources of product. Several health systems who rely on Cardinal Health for a majority of product have reported impacts including cancellation of elective surgeries as they remove product from rotation.

-
Daily Operational Schedule:

0800 – SOC IST Start Shift Brief

0830 – FEMA Daily Operations Briefing

1230 – FEMA Interagency Teleconference – Puerto Rico Earthquake

1330 – ASPR Leadership Coordination Call – Puerto Rico Earthquake

1700 – SOC IST End Shift Brief

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19

Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level III (Virtual)

CDC EOC: Level III (Polio/Ebola/Lung Injury)

FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 29Feb20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 79)

ASPR: 12 – (3) Irma/Maria, (1) 2018 California Wildfires, (8) 2020 Earthquake Puerto Rico

CDC: 67 – (25) Polio, (40) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR

Active Situations (7):

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- □ Novel Coronavirus, China

- ☐Bravo Response
- ☐Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: EW (Nights)

NRCC: ROC/Gold (Days)

National IMATs: Red – Fully Mission Capable; Blue – Deployed - PR; Gold – Deployed - PR

Regional IMATs: Region I, PR; Region II, PR; Region VIII, SD

Significant National Weather:

Freezing rain possible for portions of the TX and OK panhandles, northern AR, much of the Central Plains and southeastern SD. Heavy snow forecast for higher elevations of the Southern/Central Rockies, Sierra Nevada, and Cascade mountains. Heavy rain/thunderstorms possible for California, Pacific Northwest, and much of the Southern Plains.

3. OPDIV/STAFFDIV Overnight Reports:

CDC:

- ☐The Democratic Republic of the Congo – Update

FDA:

- ☐*Listeria monocytogenes*/Leafy Greens (suspect)/ Dec 2019
- ☐Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- ☐Salmonella Saintpaul (1912MLJN6-1)/Fruit (suspect)/ Dec 2019
- ☐E. coli O157:H7/Leafy greens (suspect)/ Dec 2019

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response (ASPR)

200 Independence Ave., S.W.

Washington, D.C. 20201

Office: (202) 619 – 7800

Fax: (202) 619 – 8602

Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received

this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/16 07:59:01
Delivered Date:	2020/01/16 07:59:08

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	(Correction) HHS Executive Summary 17Jan20
Date:	2020/01/16 07:59:08
Priority:	Normal
Type:	Note

HHS Executive Summary: Friday, 17Jan20

(Correction: See noteworthy item: Medical Gown Supplier Pending Recall and Impacts)

1. HHS

Today's Noteworthy Topics:

Earthquake, Puerto Rico

A 6.4-magnitude earthquake with numerous aftershocks of similar but lower magnitudes struck 8.4 miles south of Guayanilla, Puerto Rico at approximately 0345ET on 07Jan20. Power in PR is 99% restored approximately 6,800 customers, less than 1% of customers in PR, remain without power. One dialysis center in Yauco remains closed and under evaluation for structural damage and staff safety. HHS assessment team is in the process of demobilizing. Emergency Prescription Assistance Program (EPAP) implementation was completed on 14Jan20. Public Health Service (HHS) received a mission assignment for a Behavioral Health Team of four (4) stress counselors to provide support services to federal response workers.

Novel Coronavirus, Wuhan, China

On 15Jan20, Chinese health officials reported 41 confirmed infections with the new coronavirus; 6 patients had severe illness; one has died, and 7 patients had been discharged. The existing investigation indicate that no clear evidence of human-to-human transmission has been found, but cannot be ruled out; however, the risk is low. Environmental specimens were collected and tested in the South China Seafood Wholesale Market. As of 14Jan20, the test results found that some samples were positive for 2019-nCoV. On 13Jan20, Thailand reported a confirmed case of nCoV in a traveler from Wuhan City to Thailand. This is the first infection with 2019-nCoV outside of China. The patient is reportedly recovered but remains in isolation until testing negative for 48 hours. CDC's Division of Global Migration and Quarantine (DGMQ) continues planning for standup of traveler entry screening in San Francisco, Los Angeles and John F. Kennedy airports. CDC China office met with DHS/CBP at Mission China to discuss CDC and DHS/CBP plans for enhancing screening of passengers with Wuhan travel history at three U.S. airports that is scheduled to start this week.

Medical Gown Supplier Pending Recall and Impacts

This information may be shared with peers and partner organizations but not via publicly accessible channels.

On 15Jan20 SOC was notified by the HHS Critical Infrastructure Protection Division of a manufacturing quality issue likely to result in a nationwide recall of Cardinal Health level 3

surgical gowns and PreSource procedure kits containing those gowns. The FDA is currently working with Cardinal Health on the pending recall. Cardinal Health has notified its customers of the situation and has issued a voluntary product hold advising that affected products and packs containing the products should not be used. The issue is potential contamination and does not involve fit, form, or function of the gowns. The hold and recall are likely to cause nationwide spot shortages of product. Cardinal Health's suppliers are ramping up production volume and FDA is working with Cardinal Health to identify alternative sources of product. Several health systems who rely on Cardinal Health for a majority of product have reported impacts including cancellation of elective surgeries as they remove product from rotation.

-
Daily Operational Schedule:

0800 – SOC IST Start Shift Brief

0830 – FEMA Daily Operations Briefing

1230 – FEMA Interagency Teleconference – Puerto Rico Earthquake

1330 – ASPR Leadership Coordination Call – Puerto Rico Earthquake

1700 – SOC IST End Shift Brief

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19

Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level III (Virtual)

CDC EOC: Level III (Polio/Ebola/Lung Injury)

FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 29Feb20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 79)

ASPR: 12 – (3) Irma/Maria, (1) 2018 California Wildfires, (8) 2020 Earthquake Puerto Rico

CDC: 67 – (25) Polio, (40) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR

Active Situations (7):

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- □ Novel Coronavirus, China

- ☐Bravo Response
- ☐Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: EW (Nights)

NRCC: ROC/Gold (Days)

National IMATs: Red – Fully Mission Capable; Blue – Deployed - PR; Gold – Deployed - PR

Regional IMATs: Region I, PR; Region II, PR; Region VIII, SD

Significant National Weather:

Freezing rain possible for portions of the TX and OK panhandles, northern AR, much of the Central Plains and southeastern SD. Heavy snow forecast for higher elevations of the Southern/Central Rockies, Sierra Nevada, and Cascade mountains. Heavy rain/thunderstorms possible for California, Pacific Northwest, and much of the Southern Plains.

3. OPDIV/STAFFDIV Overnight Reports:

CDC:

- ☐The Democratic Republic of the Congo – Update

FDA:

- ☐*Listeria monocytogenes*/Leafy Greens (suspect)/ Dec 2019
- ☐Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- ☐Salmonella Saintpaul (1912MLJN6-1)/Fruit (suspect)/ Dec 2019
- ☐E. coli O157:H7/Leafy greens (suspect)/ Dec 2019

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response (ASPR)

200 Independence Ave., S.W.

Washington, D.C. 20201

Office: (202) 619 – 7800

Fax: (202) 619 – 8602

Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received

this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/16 07:59:01
Delivered Date:	2020/01/16 07:59:08
Message Flags:	Unread

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	(Correction #2) HHS Executive Summary 16Jan20
Date:	2020/01/16 09:01:28
Priority:	Normal
Type:	Note

HHS Executive Summary: Thursday, 16Jan20

(Correction # 2): See noteworthy item: Medical Gown Supplier Pending Recall and Impacts and Date

1. HHS

Today's Noteworthy Topics:

Earthquake, Puerto Rico

A 6.4-magnitude earthquake with numerous aftershocks of similar but lower magnitudes struck 8.4 miles south of Guayanilla, Puerto Rico at approximately 0345ET on 07Jan20. Power in PR is 99% restored approximately 6,800 customers, less than 1% of customers in PR, remain without power. One dialysis center in Yauco remains closed and under evaluation for structural damage and staff safety. HHS assessment team is in the process of demobilizing. Emergency Prescription Assistance Program (EPAP) implementation was completed on 14Jan20. Public Health Service (HHS) received a mission assignment for a Behavioral Health Team of four (4) stress counselors to provide support services to federal response workers.

Novel Coronavirus, Wuhan, China

On 15Jan20, Chinese health officials reported 41 confirmed infections with the new coronavirus; 6 patients had severe illness; one has died, and 7 patients had been discharged. The existing investigation indicate that no clear evidence of human-to-human transmission has been found, but cannot be ruled out; however, the risk is low. Environmental specimens were collected and tested in the South China Seafood Wholesale Market. As of 14Jan20, the test results found that some samples were positive for 2019-nCoV. On 13Jan20, Thailand reported a confirmed case of nCoV in a traveler from Wuhan City to Thailand. This is the first infection with 2019-nCoV outside of China. The patient is reportedly recovered but remains in isolation until testing negative for 48 hours. CDC's Division of Global Migration and Quarantine (DGMQ) continues planning for standup of traveler entry screening in San Francisco, Los Angeles and John F. Kennedy airports. CDC China office met with DHS/CBP at Mission China to discuss CDC and DHS/CBP plans for enhancing screening of passengers with Wuhan travel history at three U.S. airports that is scheduled to start this week.

Medical Gown Supplier Pending Recall and Impacts **TLP Green: May be shared with peers and partner organizations but not via publicly accessible channels"**

On 15Jan20 SOC was notified by the HHS Critical Infrastructure Protection Division of a manufacturing quality issue likely to result in a nationwide recall of Cardinal Health level 3 surgical gowns and PreSource procedure kits containing those gowns. The FDA is currently

working with Cardinal Health on the pending recall. Cardinal Health has notified its customers of the situation and has issued a voluntary product hold advising that affected products and packs containing the products should not be used. The issue is potential contamination and does not involve fit, form, or function of the gowns. The hold and recall are likely to cause nationwide spot shortages of product. Cardinal Health's suppliers are ramping up production volume and FDA is working with Cardinal Health to identify alternative sources of product. Several health systems who rely on Cardinal Health for a majority of product have reported impacts including cancellation of elective surgeries as they remove product from rotation.

Daily Operational Schedule:

0800 – SOC IST Start Shift Brief
0830 – FEMA Daily Operations Briefing
1230 – FEMA Interagency Teleconference – Puerto Rico Earthquake
1330 – ASPR Leadership Coordination Call – Puerto Rico Earthquake
1700 – SOC IST End Shift Brief

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19
Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level III (Virtual)
CDC EOC: Level III (Polio/Ebola/Lung Injury)
FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated
ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 29Feb20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 79)

ASPR: 12 – (3) Irma/Maria, (1) 2018 California Wildfires, (8) 2020 Earthquake Puerto Rico
CDC: 67 – (25) Polio, (40) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR

Active Situations (7):

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- □ Novel Coronavirus, China
- □ Bravo Response

- ☐Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: EW (Nights)

NRCC: ROC/Gold (Days)

National IMATs: Red – Fully Mission Capable; Blue – Deployed - PR; Gold – Deployed - PR

Regional IMATs: Region I, PR; Region II, PR; Region VIII, SD

Significant National Weather:

Freezing rain possible for portions of the TX and OK panhandles, northern AR, much of the Central Plains and southeastern SD. Heavy snow forecast for higher elevations of the Southern/Central Rockies, Sierra Nevada, and Cascade mountains. Heavy rain/thunderstorms possible for California, Pacific Northwest, and much of the Southern Plains.

3. OPDIV/STAFFDIV Overnight Reports:

CDC:

- ☐The Democratic Republic of the Congo – Update

FDA:

- ☐*Listeria monocytogenes*/Leafy Greens (suspect)/ Dec 2019
- ☐Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- ☐Salmonella Saintpaul (1912MLJN6-1)/Fruit (suspect)/ Dec 2019
- ☐E. coli O157:H7/Leafy greens (suspect)/ Dec 2019

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response (ASPR)

200 Independence Ave., S.W.

Washington, D.C. 20201

Office: (202) 619 – 7800

Fax: (202) 619 – 8602

Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/16 09:01:20
Delivered Date:	2020/01/16 09:01:28

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=1D8863B643654B1AAD9A38C952AF613E-MANGO, PAUL>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>
CC:	Watters, Sam (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d924dea65e5c4c098e0cb3fc363a2062-Watters, Sa>
Subject:	Fwd: DRAFT: HHS Night Note
Date:	2020/01/16 18:39:34
Priority:	Normal
Type:	Note

Sam- Brian or Judy will need to sign off on it tonight

Sent from my iPhone

Begin forwarded message:

From: "Watters, Sam (HHS/IOS)" <Sam.Watters@hhs.gov>
Date: January 16, 2020 at 6:26:45 PM EST
To: "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>
Subject: DRAFT: HHS Night Note

Red is suggested cuts, green is suggested insertions:

(b)(5)

(b)(5)

(b)(5)

Sam Watters
Special Assistant to the Chief of Staff
Immediate Office of the Secretary
U.S. Department of Health and Human Services

(b)(6) cell

Sender:	Mango, Paul (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1D8863B643654B1AAD9A38C952AF613E-MANGO, PAUL>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Watters, Sam (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d924dea65e5c4c098e0cb3fc363a2062-Watters, Sa>
Sent Date:	2020/01/16 18:39:32
Delivered Date:	2020/01/16 18:39:34
Message Flags:	Unread

From:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
To:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Subject:	IOS Nightly Update
Date:	2020/01/16 18:50:39
Priority:	Normal
Type:	Note

Sent to White House (Night Note):

- **CDC monitoring 2019 novel coronavirus outbreak and will begin airport screening**

CDC is closely monitoring the current outbreak that was caused by a novel (new) coronavirus in Wuhan City, Hubei Province, China and is working with the World Health Organization. CDC is planning to begin active screening to identify ill patients at JFK International Airport in New York City, Los Angeles International Airport, and San Francisco International Airport for returning travelers from Wuhan, China.

- **CDC released updated lung injury cases and deaths**

As of January 14, 2020, 2,668 hospitalized e-cigarette, or vaping, product use associated lung injury (EVALI) cases have been reported to CDC from 50 states, the District of Columbia, and two U.S. territories (Puerto Rico and U.S. Virgin Islands). Sixty deaths have been confirmed in 27 states and the District of Columbia.

- **CDC to tentatively release *Morbidity and Mortality Weekly Report* on E-cigarette, or Vaping, Product Use–Associated Lung Injuries (EVALI) characteristics**

Tomorrow, CDC is expected to release a report entitled “Update: Characteristics of a Nationwide Outbreak of EVALI — United States, August 2019–January 2020.” Overall, 82% of EVALI patients reported using any THC-containing e-cigarette or vaping products, and 57% reported using any nicotine-containing products; 34% reported exclusive THC-containing product use, and 15% reported exclusive nicotine-containing product use.

- **CDC to tentatively release *Morbidity and Mortality Weekly Report* on interviewed EVALI persons**

Tomorrow, CDC is expected to release a report entitled “EVALI Among Interviewed Persons Who Report Using Only Nicotine-Containing E-cigarette, or Vaping, Products — Illinois, August 2019–December 2019.” Patients with no indication of any THC use were more likely to be older and female, and less likely to experience constitutional symptoms or to present with leukocytosis.

- **CMS 2019 Accomplishments Blog**

Tomorrow, CMS will post a blog authored by Administrator Verma highlighting the agency's accomplishments in 2019. The blog will be posted on [Cms.gov](https://www.cms.gov). There will be social media covering this item, but no other planned media.

Other Newsworthy Items:

- ACF will publish reports on Sexual Abuse and Sexual Harassment Involving Unaccompanied Alien Children: 2015, 2016, & 2017
 - ASPA has prepared reactive response and one exclusive story
- CDC will publish three articles on EVALI/vaping:
 - The first MMWR report updates EVALI patient demographic and self-reported substance use characteristics. As of January 14, 82% of EVALI patients nationwide with available data reported using any THC-containing e-cigarette, or vaping, products, and 57% reported using any nicotine-containing products; 33% reported exclusive THC-containing product use, and 14% reported exclusive nicotine-containing product use.
 - The second MMWR report summarizes characteristics of EVALI patients in Illinois by substances used in e-cigarette, or vaping, products. The study found that while most Illinois EVALI patients reported use of THC-containing products, a small percentage had no evidence of any use of THC-containing e-cigarette, or vaping, products. Of 121 interviewed EVALI patients in Illinois, nine reported using only nicotine-containing products and had no indication of any THC use.
 - A third CDC publication, a commentary titled, *A Tale of Two Epidemics: The Rise of Vaping in the United States and Implications for Public Health*, will publish in New England Journal of Medicine
- CDC is expected to announce that it will begin entry screening at selected U.S. airports of all passengers arriving from Wuhan Province in China to look for potential cases of the novel coronavirus that has been identified in a group of patients in that province
- OIG will post the following report:
 - Florida's Refugee Medical Assistance Payments Were Generally Allowable (A-04-18-02010)
- NIH will send the press release, "Effective clinical diagnostic instruments for assessing autism

From Today:

- OIG posted the following report:
 - [CMS's Controls Over Assigning Medicare Beneficiary Identifiers and Mailing New Medicare Cards Were Generally Effective but Could Be Improved in Some Areas \(A-09-19-03003\)](#)
- (OCR) [HHS OCR Secures Voluntary Resolution with CHRISTUS Trinity Mother Frances Health System to Strengthen its Provision of Auxiliary Aids and Services to Individuals Who Are Deaf or Hard of Hearing](#)
- (CDC) [CDC Maps America's High Levels of Inactivity](#)

- (CDC) [CDC, States Update Number of Hospitalized EVALI Cases and EVALI Deaths](#)
- (FDA) [Statement on quality issues with certain Cardinal Health surgical gowns and packs](#)
- (NIH) [Patients with newly diagnosed musculoskeletal pain are prescribed opioids more often than recommended](#)

Notable Coverage:

[HHS Secretary Alex Azar says 'no international right to abortion'](#)
Washington Times // Christopher Vondracek

[HHS proposes ending referral requirement for faith-based providers](#)
Modern Healthcare // Harris Meyer

[Can your child pray at school? Trump celebrates students at Religious Freedom Day event](#)
Deseret News // Kelsey Dallas

Sam Watters
Special Assistant to the Chief of Staff
Immediate Office of the Secretary
U.S. Department of Health and Human Services

(b)(6) cell

Sender:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
Recipient:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Sent Date:	2020/01/16 18:50:38
Delivered Date:	2020/01/16 18:50:39
Message Flags:	Unread

From:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
To:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Subject:	IOS Nightly Update
Date:	2020/01/16 18:50:40
Priority:	Normal
Type:	Note

Sent to White House (Night Note):

- CDC monitoring 2019 novel coronavirus outbreak and will begin airport screening**
 CDC is closely monitoring the current outbreak that was caused by a novel (new) coronavirus in Wuhan City, Hubei Province, China and is working with the World Health Organization. CDC is planning to begin active screening to identify ill patients at JFK International Airport in New York City, Los Angeles International Airport, and San Francisco International Airport for returning travelers from Wuhan, China.
- CDC released updated lung injury cases and deaths**
 As of January 14, 2020, 2,668 hospitalized e-cigarette, or vaping, product use associated lung injury (EVALI) cases have been reported to CDC from 50 states, the District of Columbia, and two U.S. territories (Puerto Rico and U.S. Virgin Islands). Sixty deaths have been confirmed in 27 states and the District of Columbia.
- CDC to tentatively release *Morbidity and Mortality Weekly Report* on E-cigarette, or Vaping, Product Use–Associated Lung Injuries (EVALI) characteristics**
 Tomorrow, CDC is expected to release a report entitled “Update: Characteristics of a Nationwide Outbreak of EVALI — United States, August 2019–January 2020.” Overall, 82% of EVALI patients reported using any THC-containing e-cigarette or vaping products, and 57% reported using any nicotine-containing products; 34% reported exclusive THC-containing product use, and 15% reported exclusive nicotine-containing product use.
- CDC to tentatively release *Morbidity and Mortality Weekly Report* on interviewed EVALI persons**
 Tomorrow, CDC is expected to release a report entitled “EVALI Among Interviewed Persons Who Report Using Only Nicotine-Containing E-cigarette, or Vaping, Products — Illinois, August 2019–December 2019.” Patients with no indication of any THC use were more likely to be older and female, and less likely to experience constitutional symptoms or to present with leukocytosis.
- CMS 2019 Accomplishments Blog**

Tomorrow, CMS will post a blog authored by Administrator Verma highlighting the agency's accomplishments in 2019. The blog will be posted on [Cms.gov](https://www.cms.gov). There will be social media covering this item, but no other planned media.

Other Newsworthy Items:

- ACF will publish reports on Sexual Abuse and Sexual Harassment Involving Unaccompanied Alien Children: 2015, 2016, & 2017
 - ASPA has prepared reactive response and one exclusive story
- CDC will publish three articles on EVALI/vaping:
 - The first MMWR report updates EVALI patient demographic and self-reported substance use characteristics. As of January 14, 82% of EVALI patients nationwide with available data reported using any THC-containing e-cigarette, or vaping, products, and 57% reported using any nicotine-containing products; 33% reported exclusive THC-containing product use, and 14% reported exclusive nicotine-containing product use.
 - The second MMWR report summarizes characteristics of EVALI patients in Illinois by substances used in e-cigarette, or vaping, products. The study found that while most Illinois EVALI patients reported use of THC-containing products, a small percentage had no evidence of any use of THC-containing e-cigarette, or vaping, products. Of 121 interviewed EVALI patients in Illinois, nine reported using only nicotine-containing products and had no indication of any THC use.
 - A third CDC publication, a commentary titled, *A Tale of Two Epidemics: The Rise of Vaping in the United States and Implications for Public Health*, will publish in New England Journal of Medicine
- CDC is expected to announce that it will begin entry screening at selected U.S. airports of all passengers arriving from Wuhan Province in China to look for potential cases of the novel coronavirus that has been identified in a group of patients in that province
- OIG will post the following report:
 - Florida's Refugee Medical Assistance Payments Were Generally Allowable (A-04-18-02010)
- NIH will send the press release, "Effective clinical diagnostic instruments for assessing autism

From Today:

- OIG posted the following report:
 - [CMS's Controls Over Assigning Medicare Beneficiary Identifiers and Mailing New Medicare Cards Were Generally Effective but Could Be Improved in Some Areas \(A-09-19-03003\)](#)
- (OCR) [HHS OCR Secures Voluntary Resolution with CHRISTUS Trinity Mother Frances Health System to Strengthen its Provision of Auxiliary Aids and Services to Individuals Who Are Deaf or Hard of Hearing](#)
- (CDC) [CDC Maps America's High Levels of Inactivity](#)

- (CDC) [CDC, States Update Number of Hospitalized EVALI Cases and EVALI Deaths](#)
- (FDA) [Statement on quality issues with certain Cardinal Health surgical gowns and packs](#)
- (NIH) [Patients with newly diagnosed musculoskeletal pain are prescribed opioids more often than recommended](#)

Notable Coverage:

[HHS Secretary Alex Azar says 'no international right to abortion'](#)
Washington Times // Christopher Vondracek

[HHS proposes ending referral requirement for faith-based providers](#)
Modern Healthcare // Harris Meyer

[Can your child pray at school? Trump celebrates students at Religious Freedom Day event](#)
Deseret News // Kelsey Dallas

Sam Watters
Special Assistant to the Chief of Staff
Immediate Office of the Secretary
U.S. Department of Health and Human Services

(b)(6) cell

Sender:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
Recipient:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Sent Date:	2020/01/16 18:50:38
Delivered Date:	2020/01/16 18:50:40

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
To:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>
CC:	EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	Secretary's Nightly Update
Date:	2020/01/16 19:24:24
Priority:	Normal
Type:	Note

Sent to White House (Night Note):

- **CDC monitoring 2019 novel coronavirus outbreak and will begin airport screening**

CDC is closely monitoring the current outbreak that was caused by a novel (new) coronavirus in Wuhan City, Hubei Province, China and is working with the World Health Organization. CDC is planning to begin active screening to identify ill patients at JFK International Airport in New York City, Los Angeles International Airport, and San Francisco International Airport for returning travelers from Wuhan, China.

- **CDC released updated lung injury cases and deaths**

As of January 14, 2020, 2,668 hospitalized e-cigarette, or vaping, product use associated lung injury (EVALI) cases have been reported to CDC from 50 states, the District of Columbia, and two U.S. territories (Puerto Rico and U.S. Virgin Islands). Sixty deaths have been confirmed in 27 states and the District of Columbia.

- **CDC to tentatively release *Morbidity and Mortality Weekly Report* on E-cigarette, or Vaping, Product Use–Associated Lung Injuries (EVALI) characteristics**

Tomorrow, CDC is expected to release a report entitled “Update: Characteristics of a Nationwide Outbreak of EVALI — United States, August 2019–January 2020.” Overall, 82% of EVALI patients reported using any THC-containing e-cigarette or vaping products, and 57% reported using any nicotine-containing products; 34% reported exclusive THC-containing product use, and 15% reported exclusive nicotine-containing product use.

- **CDC to tentatively release *Morbidity and Mortality Weekly Report* on interviewed EVALI persons**

Tomorrow, CDC is expected to release a report entitled “EVALI Among Interviewed Persons Who Report Using Only Nicotine-Containing E-cigarette, or Vaping, Products — Illinois, August 2019–December 2019.” Patients with no indication of any THC use were more likely to be older and female, and less likely to experience constitutional symptoms or to present with leukocytosis.

- **CMS 2019 Accomplishments Blog**

Tomorrow, CMS will post a blog authored by Administrator Verma highlighting the agency's accomplishments in 2019. The blog will be posted on [Cms.gov](https://www.cms.gov). There will be social media covering this item, but no other planned media.

Other Newsworthy Items:

- • ACF will publish reports on Sexual Abuse and Sexual Harassment Involving Unaccompanied Alien Children: 2015, 2016, & 2017
 - • ASPA has prepared reactive response and one exclusive story
- • CDC will publish three articles on EVALI/vaping:
 - • The first MMWR report updates EVALI patient demographic and self-reported substance use characteristics. As of January 14, 82% of EVALI patients nationwide with available data reported using any THC-containing e-cigarette, or vaping, products, and 57% reported using any nicotine-containing products; 33% reported exclusive THC-containing product use, and 14% reported exclusive nicotine-containing product use.
 - • The second MMWR report summarizes characteristics of EVALI patients in Illinois by substances used in e-cigarette, or vaping, products. The study found that while most Illinois EVALI patients reported use of THC-containing products, a small percentage had no evidence of any use of THC-containing e-cigarette, or vaping, products. Of 121 interviewed EVALI patients in Illinois, nine reported using only nicotine-containing products and had no indication of any THC use.
 - • A third CDC publication, a commentary titled, *A Tale of Two Epidemics: The Rise of Vaping in the United States and Implications for Public Health*, will publish in New England Journal of Medicine
- • CDC is expected to announce that it will begin entry screening at selected U.S. airports of all passengers arriving from Wuhan Province in China to look for potential cases of the novel coronavirus that has been identified in a group of patients in that province
- • OIG will post the following report:
 - • Florida's Refugee Medical Assistance Payments Were Generally Allowable (A-04-18-02010)
- • NIH will send the press release, "Effective clinical diagnostic instruments for assessing autism

From Today:

- • OIG posted the following report:
 - • CMS's Controls Over Assigning Medicare Beneficiary Identifiers and Mailing New Medicare Cards Were Generally Effective but Could Be Improved in Some Areas (A-09-19-03003)

- • (OCR) HHS OCR Secures Voluntary Resolution with CHRISTUS Trinity Mother Frances Health System to Strengthen its Provision of Auxiliary Aids and Services to Individuals Who Are Deaf or Hard of Hearing
- • (CDC) CDC Maps America's High Levels of Inactivity
- • (CDC) CDC, States Update Number of Hospitalized EVALI Cases and EVALI Deaths
- • (FDA) Statement on quality issues with certain Cardinal Health surgical gowns and packs
- • (NIH) Patients with newly diagnosed musculoskeletal pain are prescribed opioids more often than recommended

Notable Coverage:

HHS Secretary Alex Azar says 'no international right to abortion'
Washington Times // Christopher Vondracek

HHS proposes ending referral requirement for faith-based providers
Modern Healthcare // Harris Meyer

Can your child pray at school? Trump celebrates students at Religious Freedom Day event
Deseret News // Kelsey Dallas

Sam Watters
Special Assistant to the Chief of Staff
Immediate Office of the Secretary
U.S. Department of Health and Human Services

(b)(6) cell

Sender:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
Recipient:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/01/16 19:24:23

Delivered Date: 2020/01/16 19:24:24

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.YDIBOHF23SPDLT)/CN=RECIPIENTS/CN=106DB0AC70A241A8B1323647C093D9BF-ARBES, SARA>
To:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>
CC:	Pratt, Michael (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8eed0423de458d801882c30fd16c99-Pratt, Mich>; Hall, Bill (HHS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02b39f27f3b4469a960054b23545cc24-Hall, Bill>; Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>; Oakley, Caitlin B. (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ee4c35534c4af9bdac46789c034790-Oakley, Cai>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>
Subject:	Re: Feinstein tweet to @secazar re: letter on coronavirus
Date:	2020/01/17 14:36:05
Priority:	Normal
Type:	Note

We received the letter yesterday. It was referred to CDC to respond.

On Jan 17, 2020, at 2:30 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>wrote:

Plus Danielle and Brian and Paul

Sent from my iPhone

On Jan 17, 2020, at 2:26 PM, Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>wrote:

<https://twitter.com/senfeinstein/status/1218252929515294728?s=21>

Sent from my iPhone

Sender:	Arbes, Sarah (HHS/ASL) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=106DB0AC70A241A8B1323647C093D9BF-ARBES, SARA>
Recipient:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Pratt, Michael (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8eed0423de458d801882c30fd16c99-Pratt, Mich>; Hall, Bill (HHS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02b39f27f3b4469a960054b23545cc24-Hall, Bill>; Murphy, Ryan (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya>; Oakley, Caitlin B. (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ee4c35534c4af9bdac46789c034790-Oakley, Cai>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Pence, Laura (HHS/ASL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1027e80d2334093870fdb436c5576cd-Pence, Laur>
Sent Date:	2020/01/17 14:36:03
Delivered Date:	2020/01/17 14:36:05
Message Flags:	Unread

From:	Peter Smith <(b)(6)>
To:	Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>
CC:	The United States House of Representatives <congressmannadler@mail.house.gov>
Subject:	INTERNATIONAL DISEASE OUTBREAK ORIGINATING IN CHINA ALERT
Date:	2020/01/17 19:01:21
Priority:	Normal
Type:	Note

Eric Hargan

The Dangerous 21st Century: Computer & Real Viruses

Health authorities still don't know what's causing the mysterious, weeks-old pneumonia outbreak that has sickened dozens in Wuhan, the capital of China's central Hubei province and home to 19 million people. Pneumonia is a serious respiratory infection usually triggered by the flu virus, but this illness is caused by an unknown pathogen. The outbreak, announced on December 31, was first thought to be linked to a food market where vendors peddle seafood and animals like birds and rabbits, leading to speculation that a new disease could have made the leap across species from animals to humans.

The infection had also spread internationally. **The first case involved a 61-year-old Chinese woman in Thailand** who had traveled to Bangkok from Wuhan. She presented with a fever on January 5, several days before Chinese officials announced the outbreak was likely caused by a new coronavirus in the same family of viruses as SARS. The deadly SARS virus, discovered in China in 2003, had jumped from civet cats to humans, then spread to two dozen countries, eventually killing 774 people and infecting more than 8,000.

This latest virus has now made its second international appearance — in Japan. The patient is a Chinese man in his 30s who returned to his home in Tokyo after visiting Wuhan. But significantly, neither of the two travelers had visited the food market linked to other cases.

Now Wuhan officials are reporting evidence of viral spread within one family — a husband who worked at the market, and his wife who hadn't visited the market. This could mean the virus has potential to spread from person to person, which could massively expand the scope of the outbreak.

- • What You Should Know About The New Strain Of Coronavirus In China (NPR)
- • China's birthrate falls to lowest level despite push for more babies(Guardian)
- • China's economic growth hits 30-year low (BBC)
- • Yosemite national park: 170 recent visitors suffer norovirus symptoms(Guardian)
- • Letting Go: What should medicine do when it can't save your life?(New Yorker, \$)

cc: SFU
cc: Anghor Hospital
cc: EU
cc: Her Majesty the Queen
cc: Balkans
cc: General Miller
cc: PMO
cc: Her Majesty the Queen
cc: Africa

Mr. Peter Smith Chief Executive Officer
CAVE MAN ENVIRONMENTAL CONSULTING

Bringing rational decision making back to Government
E Mail: (b)(6)

(b)(6)

Sender:	(b)(6)
Recipient:	Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>; The United States House of Representatives <congressmannadler@mail.house.gov>
Sent Date:	2020/01/17 19:01:10
Delivered Date:	2020/01/17 19:01:21

From:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
To:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Subject:	IOS Nightly Note
Date:	2020/01/17 19:39:04
Priority:	Normal
Type:	Note

Sent to White House (HHS Night Note):

(None)

Other Newsworthy Items:

- Monday, NIH will send the press release, “Combined prenatal smoking and drinking greatly increases SIDS risk”
- Tuesday, CDC will publish the 2018 Federal Select Agent Program Annual Report

From Today:

- Deputy Secretary Hargan participated in a podcast interview with Anne Schieber of the Heartland Institute re: Regulatory Sprint to Coordinated Care
- (CDC) Public Health Screening to Begin at 3 U.S. Airports for 2019 Novel Coronavirus (“2019-nCoV”)
- (CDC) Telebriefing: Updated on 2019 Novel Coronavirus (2019-nCoV)
- (CDC) Most EVALI patients used THC-containing products as new cases continue to decline
- (ACL) NIDILRR forecasting several research funding opportunities
- (ACL) National coalition on mental health and aging webinar: solutions to behavior health workforce shortages and lack of funding
- OIG will post the following report:

- Florida's Refugee Medical Assistance Payments Were Generally Allowable (A-04-18-02010)

Notable Coverage:

HHS reports 135 sexual misconduct incidents involving 'unaccompanied alien minors'

Fox News // Sam Dorman

The Indian Health Service Is Reforming
Wall Street Journal // Michael Weahkee

Supreme Court will again review Obamacare birth control mandate
Politico Pro // Susannah Luthi

Federal Workers Profit From Tobacco and Oil, Even If They Don't Want To
New York Times // Rob Lieber

'No international right to abortion' says HHS Secretary
Catholic News Agency // No Byline

HHS PROPOSED RULE WOULD END REFERRAL MANDATE FOR FAITH-BASED PROVIDERS

HealthLeaders // John Commins

Sender:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
Recipient:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Sent Date:	2020/01/17 19:39:00
Delivered Date:	2020/01/17 19:39:04

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
To:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>
CC:	EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	Secretary's Nightly Update
Date:	2020/01/17 20:41:10
Priority:	Normal
Type:	Note

Sent to White House (HHS Night Note):

(None)

Other Newsworthy Items:

- Monday, NIH will send the press release, "Combined prenatal smoking and drinking greatly increases SIDS risk"
- Tuesday, CDC will publish the 2018 Federal Select Agent Program Annual Report

From Today:

- Deputy Secretary Hargan participated in a podcast interview with Anne Schieber of the Heartland Institute re: Regulatory Sprint to Coordinated Care
- (CDC) [Public Health Screening to Begin at 3 U.S. Airports for 2019 Novel Coronavirus \("2019-nCoV"\)](#)
- (CDC) [Telebriefing: Updated on 2019 Novel Coronavirus \(2019-nCoV\)](#)
- (CDC) [Most EVALI patients used THC-containing products as new cases continue to decline](#)
- (ACL) [NIDILRR forecasting several research funding opportunities](#)
- (ACL) [National coalition on mental health and aging webinar: solutions to behavior health workforce shortages and lack of funding](#)
- OIG will post the following report:

- Florida's Refugee Medical Assistance Payments Were Generally Allowable (A-04-18-02010)

Notable Coverage:

HHS reports 135 sexual misconduct incidents involving 'unaccompanied alien minors'

Fox News // Sam Dorman

The Indian Health Service Is Reforming
Wall Street Journal // Michael Weahkee

Supreme Court will again review Obamacare birth control mandate
Politico Pro // Susannah Luthi

Federal Workers Profit From Tobacco and Oil, Even If They Don't Want To
New York Times // Rob Lieber

'No international right to abortion' says HHS Secretary
Catholic News Agency // No Byline

HHS PROPOSED RULE WOULD END REFERRAL MANDATE FOR FAITH-BASED PROVIDERS

HealthLeaders // John Commins

Sender:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
Recipient:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/01/17 20:41:06
Delivered Date:	2020/01/17 20:41:10

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 18Jan20
Date:	2020/01/18 07:33:12
Priority:	Normal
Type:	Note

HHS Executive Summary: Saturday, 18Jan20

1. HHS

Today's Noteworthy Topics:

2019-2020 Influenza Season, United States

Key indicators that track flu activity declined slightly but remain high. Indicators that track severity (hospitalizations and deaths) are not high at this point in the season. CDC FluView presentation shows the overall hospitalization rate for the season is 19.9 per 100,000. This is similar to what has been seen at this time during other recent seasons. The Pneumonia and Influenza (P&I) Mortality Surveillance reports 6.0 % to 6.9% of deaths were attributed to pneumonia and influenza (P&I). This is below the epidemic threshold. Reports to the CDC this week stated seven new influenza-associated pediatric deaths occurring during the 2019-2020 season, with a total of 39 deaths.

2020 Earthquake, Puerto Rico

A 6.4-magnitude earthquake with numerous aftershocks of similar but lower magnitudes struck 8.4 miles south of Guayanilla, Puerto Rico at approximately 0345ET on 07Jan20. A Presidential Major Disaster Declaration was approved on 16Jan20. A HHS PHS Behavioral Health Team arrived 17Jan20 to provide support to federal response workers. The Secretary's Operations Center returned to Level IV: Normal Operations effective 17Jan20 at 1330ET, but continues to monitor and will report as needed.

Daily Operational Schedule: NSTR

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19

Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level IV (Steady State)

CDC EOC: Level III (Polio/Ebola/Lung Injury)

FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 05Mar20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 89)

ASPR: 12 – (3) Irma/Maria, (1) 2018 California Wildfires, (7) 2020 Earthquake Puerto Rico

CDC: 77 – (25) Polio, (50) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR**Active Situations (7):**

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- □ Novel Coronavirus, China
- □ Bravo Response
- □ Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR**2. FEMA:****Interagency Response Status Summary:**

NWC: EW (Nights)

NRCC: ROC/Gold (Days)

National IMATs: Red – Fully Mission Capable; Blue – Deployed – PR; Gold – Demobilizing

Regional IMATs: Region I, PR; Region II, PR; Region VIII, SD

Significant National Weather:

A winter storm will produce widespread hazardous travel conditions for the Mid to Upper Mississippi Valley, Mid-West, Great Lakes and on into the Northeast. Winter storm warnings and blizzard warning in effect, with snow totals in the 6-12 inch range and wind gusts to over 50 mph. Winds and accumulation may be higher in upper elevations. In some cases, snowfall will be up to 1 inch per hour.

3. OPDIV/STAFFDIV Overnight Reports:**CDC:**

- □ Person-to-person outbreaks of hepatitis A infections – Multiple states, 2016–2019 – Update
- □ Polio (Vaccine-derived) – Ghana – Update
- □ Polio (Vaccine-derived) – Philippines – Update
- □ Polio (Vaccine-derived) – Central African Republic – Update
- □ Measles (Rubeola) – Bangladesh – Update
- □ Polio (Vaccine-derived) – Benin – Update
- □ Polio (Vaccine-derived) – Angola – Update
- □ Polio (Wild Type) – Pakistan – Update
- □ Polio (Vaccine-derived) – Togo – Update
- □ Novel Coronavirus – Japan – Update

- □The Democratic Republic of the Congo – Update

FDA:

- □Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- *E. coli* O157:H7/Leafy Greens (suspect)/ Dec 2019
- □*Listeria monocytogenes*/Leafy Greens (suspect)/ Dec 2019
- □Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- □*E. coli* O157:H7/Produce/Nov 2019 (Incident 1)
- □Salmonella Braenderup/Unknown/Dec 2019
- □Escherichia coli O157:H7/ Frozen food item (suspect)/ Nov 2019

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
 Assistant Secretary for Preparedness and Response (ASPR)
 200 Independence Ave., S.W.
 Washington, D.C. 20201
 Office: (202) 619 – 7800
 Fax: (202) 619 – 8602
 Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/18 07:33:02
Delivered Date:	2020/01/18 07:33:12

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 18Jan20
Date:	2020/01/18 07:33:10
Priority:	Normal
Type:	Note

HHS Executive Summary: Saturday, 18Jan20

1. HHS

Today's Noteworthy Topics:

2019-2020 Influenza Season, United States

Key indicators that track flu activity declined slightly but remain high. Indicators that track severity (hospitalizations and deaths) are not high at this point in the season. CDC FluView presentation shows the overall hospitalization rate for the season is 19.9 per 100,000. This is similar to what has been seen at this time during other recent seasons. The Pneumonia and Influenza (P&I) Mortality Surveillance reports 6.0 % to 6.9% of deaths were attributed to pneumonia and influenza (P&I). This is below the epidemic threshold. Reports to the CDC this week stated seven new influenza-associated pediatric deaths occurring during the 2019-2020 season, with a total of 39 deaths.

2020 Earthquake, Puerto Rico

A 6.4-magnitude earthquake with numerous aftershocks of similar but lower magnitudes struck 8.4 miles south of Guayanilla, Puerto Rico at approximately 0345ET on 07Jan20. A Presidential Major Disaster Declaration was approved on 16Jan20. A HHS PHS Behavioral Health Team arrived 17Jan20 to provide support to federal response workers. The Secretary's Operations Center returned to Level IV: Normal Operations effective 17Jan20 at 1330ET, but continues to monitor and will report as needed.

Daily Operational Schedule: NSTR

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19

Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level IV (Steady State)

CDC EOC: Level III (Polio/Ebola/Lung Injury)

FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 05Mar20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 89)

ASPR: 12 – (3) Irma/Maria, (1) 2018 California Wildfires, (7) 2020 Earthquake Puerto Rico

CDC: 77 – (25) Polio, (50) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR**Active Situations (7):**

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- □ Novel Coronavirus, China
- □ Bravo Response
- □ Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR**2. FEMA:****Interagency Response Status Summary:**

NWC: EW (Nights)

NRCC: ROC/Gold (Days)

National IMATs: Red – Fully Mission Capable; Blue – Deployed – PR; Gold – Demobilizing

Regional IMATs: Region I, PR; Region II, PR; Region VIII, SD

Significant National Weather:

A winter storm will produce widespread hazardous travel conditions for the Mid to Upper Mississippi Valley, Mid-West, Great Lakes and on into the Northeast. Winter storm warnings and blizzard warning in effect, with snow totals in the 6-12 inch range and wind gusts to over 50 mph. Winds and accumulation may be higher in upper elevations. In some cases, snowfall will be up to 1 inch per hour.

3. OPDIV/STAFFDIV Overnight Reports:**CDC:**

- □ Person-to-person outbreaks of hepatitis A infections – Multiple states, 2016–2019 – Update
- □ Polio (Vaccine-derived) – Ghana – Update
- □ Polio (Vaccine-derived) – Philippines – Update
- □ Polio (Vaccine-derived) – Central African Republic – Update
- □ Measles (Rubeola) – Bangladesh – Update
- □ Polio (Vaccine-derived) – Benin – Update
- □ Polio (Vaccine-derived) – Angola – Update
- □ Polio (Wild Type) – Pakistan – Update
- □ Polio (Vaccine-derived) – Togo – Update
- □ Novel Coronavirus – Japan – Update

- □The Democratic Republic of the Congo – Update

FDA:

- □Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- *E. coli* O157:H7/Leafy Greens (suspect)/ Dec 2019
- □*Listeria monocytogenes*/Leafy Greens (suspect)/ Dec 2019
- □Adverse Events Possibly Linked to Vaping Products/Unknown/Aug 2019
- □*E. coli* O157:H7/Produce/Nov 2019 (Incident 1)
- □Salmonella Braenderup/Unknown/Dec 2019
- □Escherichia coli O157:H7/ Frozen food item (suspect)/ Nov 2019

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
 Assistant Secretary for Preparedness and Response (ASPR)
 200 Independence Ave., S.W.
 Washington, D.C. 20201
 Office: (202) 619 – 7800
 Fax: (202) 619 – 8602
 Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/18 07:33:02
Delivered Date:	2020/01/18 07:33:10

From:	Mike Allen <mike@axios.com>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	Axios AM: Mike's Big 6 — How Election Night could turn into a drawn-out battle — Iowa warning — Trump on Joe Burrow
Date:	2020/01/18 09:30:33
Priority:	Normal
Type:	Note



PRESENTED BY KOCH INDUSTRIES

Axios AM

By Mike Allen · Jan 18, 2020

Happy Saturday.

- • **Women's marches** are being held around the world, with organizers expecting over 1 attendees in the U.S.

🎂🎂🎂 Happy third birthday to Axios! Thank you for joining us on our mission to make the matters.

- • **The first two words** of our pre-launch manifesto were "Audience First." We work ever
- • **And thank you** to the founding colleagues who believed in us even before we had a na Gmail address for the Next Great Media Company.

1 big thing: How Election Night could turn into a drawn-out

Confidence in leaders and institutions by party

Survey of 1,003 registered voters conducted Oct. 6–8, 2019

	OVERALL		GOP	DEM	IND.
Trump	 24%		51%	4%	12%
Supreme Court	 22		30	17	17
News media	 16		6	26	10
Congress	 9		8	11	3

Data: Fox News poll of 1,003 registered voters, Oct. 6–8. Margin of error ± 3 percentage points. Chart: Naema Ahmed/Axios

If the 2020 presidential election is close enough to trigger a fight over the results, the public has little confidence in the people and institutions that no one is likely to be a trusted referee, managing editor David Nath

- • **Why it matters:** Given how tight the last few elections have been, the likelihood of a c which means the danger of a fight over the results is real, too.

The big picture: This trust crisis — flagged for us as part of a larger presentation by lobbyist E polling that shows how little confidence the public has in powerful players and institutions, incl likely to be drawn into a contested election.

- • **There's a trust chasm** over President Trump, with Republicans showing far more co and independents, according to an October Fox News poll.
- • **But there's also low trust** in the Supreme Court — especially among Democrats and Congress is at rock bottom with everybody.
- • **And yes,** the news media's trust level is abysmal too, especially with Republicans and i

Other surveys have also found more evidence of deep distrust in leaders and institutions.

- • **The Pew Research Center** found a huge partisan divide in trust in politically appointed leaders (Republicans expressed more confidence in those leaders than Democrats).

What to watch: In this kind of general atmosphere of distrust, it's easy to see how an election

- • **That could happen** if Trump contests a narrow defeat or if Trump wins and Democrats challenge the results, leading to voter suppression or other issues.
- • **If either scenario happens**, Americans' confidence in any of the possible referees will be shaken, making it harder to reach a successful resolution — and right now, confidence is a lot less than solid.
- • **One sign of concern** about a close election: The Supreme Court says it will rule before the presidential electors have to vote for the candidate who won the popular vote in their state, giving them the freedom to switch to someone else.



[Share on Facebook](#)



[Tweet this Story](#)



[Post to LinkedIn](#)



[Email](#)

2. Airports on alert for new virus



Medical staff transfer patients in Wuhan, Hubei, amid the outbreak of a pneumonia-like virus. Photo: Getty Images

A virus first reported around New Year's in China has put three U.S. airports on alert.

- • **Arrivals to San Francisco**, New York and Los Angeles airports from Wuhan, China
- Eileen Drage O'Reilly reports.

Why it matters: Coronavirus' ability to evolve means the outbreak could quickly turn from "w" and "proactive measures" should be taken, a CDC official said Friday.

- • **There are more than 40 known cases**, killing two people and with reported cases

Between the lines: Researchers are trying to determine where the virus originated, if it can be person, and how long the incubation period may be, Eileen reports.

- • **Most Wuhan patients** are linked to a large seafood and animal market, "suggesting a others did not have this exposure, which suggests "some limited person-to-person spread"
- • **Coronaviruses are particularly tricky** because they are found in animals and humans

human infections lead to human-to-human infections can be severe, as seen in SARS and

The big picture: Millions of people in China are traveling for the start of Lunar New Year on J

[f Share on Facebook](#) [Tweet this Story](#) [in Post to LinkedIn](#) [Email](#)

3. Graphic du jour: China funds the world's megaprojects



Graphic: Visual Capitalist. Used by permission.

Visual Capitalist created this stunning depiction of Chinese-backed projects from 2000–2019. AidData, a research lab at the William & Mary Global Research Institute.

- **Why it matters:** Through soft diplomacy and hard leverage, China is projecting financial influence throughout the world, with a particular emphasis on ports and other projects in Africa and



[Share on Facebook](#)



[Tweet this Story](#)



[Post to LinkedIn](#)



[Email](#)

A MESSAGE FROM KOCH INDUSTRIES

This young inventor could change daily life for millions



After being diagnosed with diabetes in 2018, this Young Visioneer designed a product that could help **diabetic patients around the world.**

4. ⚖️☐ Trump's Fox-friendly Senate trial team



Screengrab: CNN

Several White House officials told Jonathan Swan they were hoping President Trump would be named to the Senate trial team by the White House yesterday as one of the Senate trial counsels, to play a formal role.

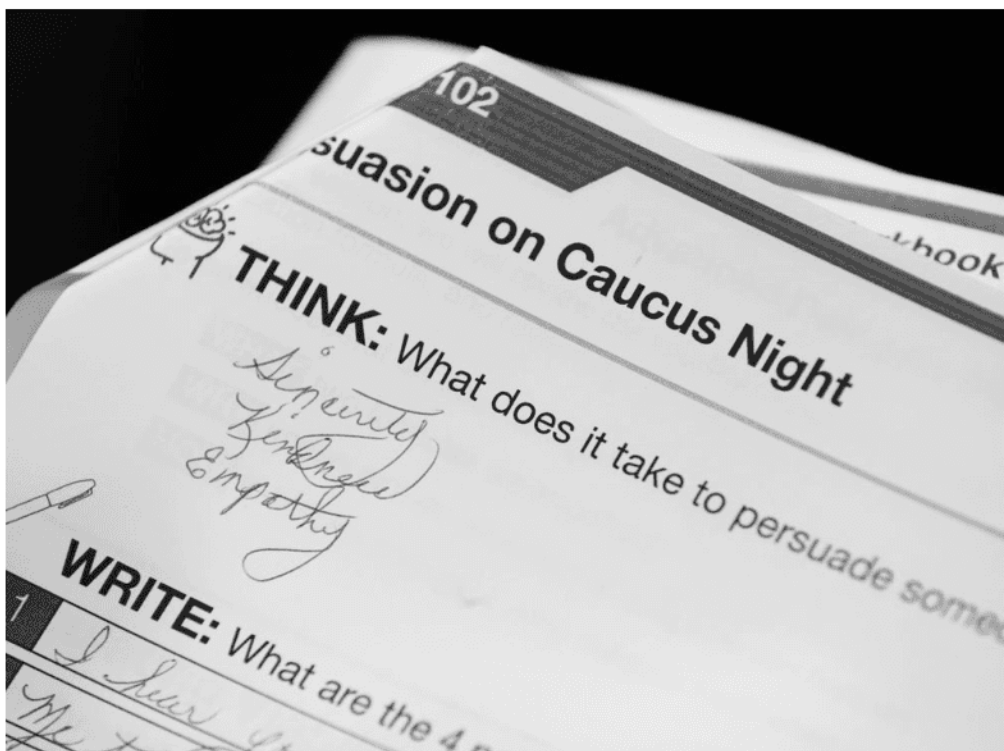
- **Why it matters:** They saw the choice as an unnecessary distraction, given that the team's lead counsel, Alan Dershowitz, has ties to Jeffrey Epstein.
- **But Trump thinks** Dershowitz is **magnificent on TV**, a White House official said.
- **Swan's bottom line:** It matters not at all who represents Trump. Republican senators will vote in his favor.

Stat du jour: Four of the team members — Ken Starr, Alan Dershowitz, Pam Bondi and Robert

weekday Fox News appearances since January 2019, according to progressive research center M

[f Share on Facebook](#) [Tweet this Story](#) [in Post to LinkedIn](#) [Email](#)

5. □□ Warning on Iowa hacking



A training booklet at the Pete Buttigieg office in Ottumwa, Iowa. Photo: Charlie Neibergall/AP

Iowa and Nevada — two of the first three states to vote in the Democratic presidential race — results from thousands of caucus sites, AP reports.

- • **Why it matters:** The technology is intended to make counting easier, but raises conce

How it works: Activists in the two states will use programs downloaded to their personal pho

gatherings to state headquarters.

- • **That data** will be used to announce the unofficial winners.
- • **Paper records** will then be used to certify the results.

Democrats are moving ahead with the technology amid warnings that foreign hackers could try to sow chaos and undermine American democracy.

- • **Party officials** say they are cognizant of the threat and taking numerous security precautions, saying the system is easily correctable because of backups.

In both states party officials declined to identify the vendor that developed their apps, saying the system is a target for hackers.



[Share on Facebook](#)



[Tweet this Story](#)



[Post to LinkedIn](#)



[Email](#)

6. 1  thing



Photo: Steve Helber/AP

Above, President Trump points out LSU quarterback Joe Burrow during an East Room ceremony.

- • **Trump,** on Heisman-winning QB Burrow: "[H]e's going to be so rich. (Laughter.) Look at Tom Brady. Does that make sense to you? We call him 'young Tom Brady.'"

Geaux deeper.



Photo: Drew Angerer/Getty Images



[Share on Facebook](#)



[Tweet this Story](#)



[Post to LinkedIn](#)



[Email](#)

A MESSAGE FROM KOCH INDUSTRIES

One way to tackle 3 million tons of electronic waste



The U.S. waste stream is overflowing with obsolete electronics. Koch employees are finding and recycling outmoded printers, cell phones and keyboards.

 **Thanks for starting your day with us.** *Please tell a friend about AM/PM.*

Axios thanks our partners for supporting our newsletters.

Sponsorship has no influence on editorial content.

Axios, 3100 Clarendon Blvd, Suite 1300, Arlington VA 22201

You received this email because you signed up for newsletters from Axios.
[Change your preferences or unsubscribe here.](#)

Was this email forwarded to you?
[Sign up now](#) to get Axios in your inbox.
And make sure you [subscribe to Mike's afternoon wrap up, Axios PM](#).

Follow Axios on social media:

[!\[\]\(339a16584d5da0f0a3ca4e9ec17bf6a1_img.jpg\) Axios on Facebook](#) [!\[\]\(e06a1d39938b2f5d7a2c3618fea4f77f_img.jpg\) Axios on Twitter](#) [!\[\]\(23ac9e28f2600a1e787d149d7f76716a_img.jpg\) Axios on Instagram](#)

Sender:	Mike Allen <mike@axios.com>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/01/18 09:30:23
Delivered Date:	2020/01/18 09:30:33

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS International FYSA: Novel Coronavirus, Wuhan, China (Update#4)
Date:	2020/01/18 14:10:07
Priority:	Normal
Type:	Note

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #4)

The current situation relates to an outbreak of Novel Coronavirus in Wuhan City, Hubei Province, China. Some patients were linked to a large local seafood and animal market.

- **On 17Jan20**, Chinese health officials reported **45** confirmed infections with the new coronavirus; **5** patients had severe illness; and **2** have died, and **15 patients have been discharged**
- **CDC surge staffing deployments as of 17Jan20: 10 at SFO, 7 at LAX, and 11 at JFK**
- **Engaged with port and community partners to discuss entry screening activities**
- **Call held with airline industry and DHS/CBP partners to finalize airport Concept of Operations documents**
Traveler Entry Screening began for flights arriving from Wuhan at John F Kennedy (JFK) airport 17Jan20
- **Continued planning for traveler entry screening at San Francisco (SFO), Los Angeles (LAX) and John F Kennedy (JFK) airports beginning the night of January 17**
- **On 17Jan20, a call was held with ASTHO, NACCHO, CSTE, APLH, and their constituents**
 - **to provide updates about implementation of airline screening and guidance for persons under investigation**
- **On 15Jan20, Japan Ministry of Health confirmed its first case of 2019-nCoV. The patient had pneumonia with a history of staying in Wuhan. When he visited a medical institution on 06Jan20, he reported his stay in Wuhan. The patient's sample was tested at the National Institute of Infectious Diseases and tested positive for 2019-nCoV on 15Jan20.**
 - **Japan is carrying out active epidemiological investigations on this matter.**
- **CDC is engaging PPE supply chain partners.**

For more details, please see attached CDC SITREP for Novel Coronavirus.

The SOC will continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Juan Ospina, Watch Officer

Approved by: Brandon W. Britton, Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
Description: Description: Description: Description: Description:
cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/18 14:09:58
Delivered Date:	2020/01/18 14:10:07

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.ROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7CD78B4810D44B17B8711AAEDE9A9023-GRIGSBY, GL>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	Fwd: Wuhan Municipal Health and Health Committee's report on pneumonia of new coronavirus infection, 2020-01-19 00:43:34 / 17 newly diagnosed cases in Wuhan 62 cases total http://bit.ly/2v4y6wd
Date:	2020/01/18 18:19:53
Priority:	Normal
Type:	Note

Brian,

I think Redfield calls to update The Sec on the regularly, but passing this along

Sent from my iPhone

Begin forwarded message:

From: "Kerr, Lawrence (HHS/OS/OGA)" <Lawrence.Kerr@hhs.gov>
Date: January 18, 2020 at 4:43:24 PM EST
To: "Grigsby, Garrett (HHS/OS/OGA)" <Garrett.Grigsby@hhs.gov>, "Zebley, Kyle (HHS/OS/OGA)" <Kyle.Zebley@hhs.gov>, "Weinberger, Collin (OS/OGA) (CTR)" <Collin.Weinberger@hhs.gov>, "Elvander, Erika (OS/OGA)" <Erika.Elvander@hhs.gov>
Subject: Wuhan Municipal Health and Health Committee's report on pneumonia of new coronavirus infection, 2020-01-19 00:43:34 / 17 newly diagnosed cases in Wuhan 62 cases total <http://bit.ly/2v4y6wd>

Some surprising news – 17 new cases identified in Wuhan. The reservoir of the virus has not been identified. Very disturbing news for the beginning of the Lunar New Year and the mass migration.

Wuhan Municipal Health and Health Committee's report on pneumonia of new coronavirus infection
Published by: Wuhan Municipal Health Commission | Release time: 2020-01-19 00:43:34

At 04:00 on January 17, 2020, 4 patients were cured and discharged, with 17 new cases and no deaths.

Analysis of the epidemiological data of the previously released cases of pneumonitis infected by the new coronavirus found that some cases had no history of contact with the South China Seafood Wholesale Market. On the basis of standardizing pre-screening triage and fever diagnosis, optimized test kits were used to sample and monitor unidentified pneumonia cases for fever diagnosis and isolation in the city, and 17 new types of coronavirus positive were detected. After comprehensive research and judgment by clinical experts, 17 cases were confirmed as confirmed cases , and all were treated in Wuhan Jinyintan Hospital and related designated hospitals . Of the 17 newly diagnosed cases, 3 were severe cases. The next step will continue to carry out the detection of suspected cases in the city.

As of 24:00 on January 17, 62 cases of pneumonitis with new coronavirus infection have been reported in our city, 19 cases have been cured and discharged, 8 cases are

being treated in severe cases, and 2 cases have died. The remaining patients are in stable condition. Institution receives isolation treatment. A total of 763 close contacts have been tracked, 681 medical observations have been lifted, and 82 people are still receiving medical observations. Among the close contacts, no related cases were found. Epidemiological investigations of new cases and follow-up investigations of close contacts are ongoing.

January 18, 2020

Sender:	Grigsby, Garrett (HHS/OS/OGA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7CD78B4810D44B17B8711AAEDE9A9023-GRIGSBY, GL>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/01/18 18:19:52
Delivered Date:	2020/01/18 18:19:53

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 19Jan20
Date:	2020/01/19 06:46:28
Priority:	Normal
Type:	Note

HHS Executive Summary: Sunday, 19Jan20

1. HHS

Today's Noteworthy Topics:

Novel Coronavirus, Wuhan, China

The current situation relates to an outbreak of Novel Coronavirus in Wuhan City, Hubei Province, China. Some patients were linked to a large local seafood and animal market. On 17Jan20, Chinese health officials reported 45 confirmed infections with the new coronavirus; 5 patients had severe illness; and 2 have died, and 15 patients have been discharged. CDC surge staffing deployments as of 17Jan20: 10 at SFO, 7 at LAX, and 11 at JFK. CDC is engaged with port and community partners to discuss entry screening activities. Traveler Entry Screening began for flights arriving from Wuhan at John F Kennedy (JFK) airport 17Jan20, San Francisco (SFO) and Los Angeles (LAX). CDC is engaging PPE supply chain partners.

Bravo Response

The Department of Homeland Security (DHS) issued a National Terrorism Advisory System (NTAS) Bulletin on Saturday 18Jan20, summarizing Iran-related terrorism threats to the United States following increased regional tensions in the Middle East. The advisory is valid through 1300 ET, 18MAR20. DHS does not have information indicating a specific, credible threat to the U.S. homeland. Iran maintains some cyber capability and is capable of at a minimum, of carrying out attacks with temporary disruptive effects against critical infrastructure in the United States. National Terrorism Advisory System advises to be prepared for a cyber-incident with an offline backup, an incident response plan, and know who to call for help. DHS will provide additional information about any emerging threat as additional information is identified.

Daily Operational Schedule: NSTR

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19

Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level IV (Steady State)

CDC EOC: Level III (Polio/Ebola/Lung Injury)

FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 05Mar20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 88)

ASPR: 11 – (3) Irma/Maria, (1) 2018 California Wildfires, (7) 2020 Earthquake Puerto Rico

CDC: 77 – (25) Polio, (50) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR

Active Situations (7):

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- □ Novel Coronavirus, China
- □ Bravo Response
- □ Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: Monitoring

NRCC: Blue

National IMATs: Red – Fully Mission Capable; Blue – Deployed – PR; Gold – Demobilizing

Regional IMATs: Region I, Demobilizing; Region II, PR; Region VIII, SD

Significant National Weather:

Ongoing winter storm across the Great Lakes and the Eastern U.S. expected to persist through today across New England. Snowfall total of 6 to 12 inches are likely from northern New York to central Maine; blizzard conditions across the Dakotas and Minnesota will abate this morning. An arctic air mass will be settling southward in the wake of the winter storm across much of the central and northern plains.

3. OPDIV/STAFFDIV Overnight Reports:

CDC: NSTR

FDA: NSTR

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave., S.W.
Washington, D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/19 06:46:21
Delivered Date:	2020/01/19 06:46:28

From:	Dulaigh, Joel (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02B15E96DC484DB29682C1D336E63441-DULAIGH, JO>
To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcbd759f5dcad91-Schwartz, E>; Wright, Janet (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f672e2527b4f44891fb4f4be08cdfd-Wright, Jan>
Subject:	FW: HHS International FYSA: Novel Coronavirus, Wuhan, China (Update#4)
Date:	2020/01/19 16:26:26
Priority:	Normal
Type:	Note

FYSA

V/R,
Joel

CAPT Joel Dulaigh, ACNP-BC, FAANP

Chief of Staff to the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
200 Independence Ave SW, Suite 701-H
Washington, DC 20201
Office Phone: 202-690-7511
Cell: (b)(6)
Direct Fax: 202.260.4405
Email: joel.dulaigh@hhs.gov

In Officio Salutis

From: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Sent: Saturday, January 18, 2020 2:10 PM
To: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Subject: HHS International FYSA: Novel Coronavirus, Wuhan, China (Update#4)

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #4)

The current situation relates to an outbreak of Novel Coronavirus in Wuhan City, Hubei Province, China. Some patients were linked to a large local seafood and animal market.

- **On 17Jan20**, Chinese health officials reported **45** confirmed infections with the new coronavirus; **5** patients had severe illness; and **2** have died, and **15 patients have been discharged**
- **CDC surge staffing deployments as of 17Jan20: 10 at SFO, 7 at LAX, and 11 at JFK**
- **Engaged with port and community partners to discuss entry screening activities**

- Call held with airline industry and DHS/CBP partners to finalize airport Concept of Operations documents
Traveler Entry Screening began for flights arriving from Wuhan at John F Kennedy (JFK) airport 17Jan20
- Continued planning for traveler entry screening at San Francisco (SFO), Los Angeles (LAX) and John F Kennedy (JFK) airports beginning the night of January 17
- On 17Jan20, a call was held with ASTHO, NACCHO, CSTE, APLH, and their constituents
 - to provide updates about implementation of airline screening and guidance for persons under investigation
- On 15Jan20, Japan Ministry of Health confirmed its first case of 2019-nCoV. The patient had pneumonia with a history of staying in Wuhan. When he visited a medical institution on 06Jan20, he reported his stay in Wuhan. The patient's sample was tested at the National Institute of Infectious Diseases and tested positive for 2019-nCoV on 15Jan20.
 - Japan is carrying out active epidemiological investigations on this matter.
- CDC is engaging PPE supply chain partners.

For more details, please see attached CDC SITREP for Novel Coronavirus.

The SOC will continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Juan Ospina, Watch Officer

Approved by: Brandon W. Britton, Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
Description: Description: Description: Description: Description:
cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	Dulaigh, Joel (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02B15E96DC484DB29682C1D336E63441-DULAIGH, JO>
Recipient:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>; Wright, Janet (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f672e2527b4f44891fb4fbe08cdfdf-Wright, Jan>
Sent Date:	2020/01/19 16:26:24
Delivered Date:	2020/01/19 16:26:26

From:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
To:	Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>; Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>; Armstrong, Kimberly (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong,>; 'Gay, Cyril' <cyril.gay@usda.gov>; 'Gay, Cyril' <Cyril.Gay@ARS.USDA.GOV>; (b)(6); (b)(6); (b)(6); <stephen.ieppia@nih.gov>; Adhya, Sankar (NIH/NCI) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fec05934ed0f42d6a24ccb8d19e1c6e5-sankar.adhy>; Biswajit Biswas PhD <biswas.biswajit.ctr@mail.mil>; 'Carl Merrill' (b)(6); <robert.bonomo@va.gov>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Khanna, Gopal (AHRQ/IOD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76eaf1c03eb347608851b240d65e1197-Khanna, Gop>; Meyers, David (AHRQ/IOD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efa09be51c1b409f9bd6cbfa4b25a7f7-Meyers, Dav>; <Rachel.Ramoni@va.gov>; <MARISUE.CODY@VA.GOV>; (b)(6); (b)(6); (b)(6);
Subject:	1-19-20 2019-nCoV 198 CASES [see evidence of limited human-to-human transmission] Wuhan nCoV outbreak quadruples, spreads within China
Date:	2020/01/19 19:31:40
Priority:	Normal
Type:	Note

<http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china>

Wuhan nCoV outbreak quadruples, spreads within China ... Jan 19, 2020

A surge of newly confirmed novel coronavirus (2019-nCoV) cases since Friday in Wuhan has pushed the outbreak total to **198 cases**, some of them with **no apparent links to the outbreak market**, and health officials today announced a case in Shenzhen, China's first outside of Wuhan.

The expansion of the outbreak in China comes during Asia's *heavy travel season ahead* of the **Jan 25** Lunar New Year observance.

Meanwhile, the World Health Organization (WHO) said yesterday officials **see evidence of** limited human-to-human transmission, adding that it's closely watching for signs of sustained spread.

Wuhan's health commission announced 17 cases yesterday, which covered illnesses confirmed on Jan 17. In a statement today, it announced a **dramatic spike in cases**, which include 59 from yesterday and 77 from today.

Of the 136 cases in today's announcement, 100 are mild, **33 are severe**, and 3 are listed as critical, including **one death**.

Three days ago, Wuhan officials said the outbreak **was only 45** cases strong.

Some cases not tied to animal market

In its update yesterday, Wuhan's health commission said new cases were identified among **unexplained pneumonia** cases at community health centers and local hospitals. The statements were translated and posted by FluTrackers, an online infectious disease news message board.

Wuhan's health commission also noted several epidemiologic details, including that an analysis of data of earlier cases found that some had **no history of contact with the seafood market** at the center of the investigation, which also sold other animals such as poultry, bats, marmots, and wild game meat.

Of the new cases announced this weekend, all involve adults ages 25 to 89. About half are male (78) and half are female (75). The latest onset date is yesterday.

Of the 198 patients confirmed so far, **28 have recovered** or been discharged. Of the 170 people still in the hospital, 126 have mild illness, **35 are listed as severe**, and **9 are in critical condition**.

Three deaths have been now reported. Hospitalized patients in Wuhan are isolated at a designated facility.

The number of close contacts under monitoring has risen from **763 to 817**, and monitoring is still under way for 90. So far no related cases have been found in contacts.

Shenzhen patient had visited Wuhan

In another development today, Guangdong province health officials announced a **2019-nCoV** infection in a 66-year-old man from Shenzhen who visited relatives in Wuhan on Dec 29, according to an official statement translated and posted by FluTrackers. The case marks the first in China outside of Wuhan, though three exported illnesses have been reported in other countries—all with ties to Wuhan.

The man's symptoms began on Jan 3, and he traveled back to Shenzhen the next day. Specimens sent to the Chinese Center for Disease Control and Prevention (China CDC) tested positive yesterday. The patient is in isolation at a hospital, where he is in stable condition.

Shenzhen is China's fourth-largest city, with a population of about **12.5 million**, and is about **550 air miles** from Wuhan. Shenzhen lies adjacent to Hong Kong.

WHO on watch for sustained spread

Yesterday after Wuhan officials announced the **initial spurt of 17 cases**, the WHO's Western Pacific regional office (WHO WPRO) said the new cases were found thanks to enhanced surveillance, some with **no apparent links** to the seafood market. It said the Chinese government last week called for broader screening for nCoV and that cases may be identified in other cities in the days and weeks ahead.

Based on WHO's latest analysis, there is **evidence of limited** human-to-human **spread**, the agency said, adding that the pattern is similar to **other** respiratory illnesses, especially **other** coronavirus outbreaks.

Though there is **no clear evidence** of **sustained transmission**, meaning the virus **spreads easily** and isn't limited to clusters, the WHO said it doesn't have enough information to fully assess the extent of transmission. "This is one of the issues that WHO is monitoring closely," it said. The organization also urged countries to **continue their preparedness activities**.

Where's the animal reservoir?

Michael T. Osterholm, PhD, MPH, said the new developments in the outbreak fit with a recent prediction from Imperial College London that Wuhan probably has many more cases than previously reported and that sustained transmission **shouldn't be ruled out**.

Osterholm is director of the University of Minnesota's Center for Infectious Disease Research and Policy, which publishes CIDRAP News.

It's not surprising to see a slew of more cases, he said, and if the earlier cases were the **tip of the iceberg**, health officials have now uncovered more of the iceberg.

Though it's good that 2019-nCoV mainly shows a mild illness spectrum, and so far there's **no evidence of a superspreading event**, there are **still so many unknowns**, Osterholm said.

"We still need to understand the reservoir," he said. As 2019-nCoV infections pop up in more Chinese towns, Osterholm said officials will closely be watching for travel links to Wuhan—as well as the possibility that the animal reservoir that triggered the outbreak may be in live-animal markets in other Chinese cities.

<http://www.cidrap.umn.edu/news-perspective/2020/01/japan-has-1st-novel-coronavirus-case-china-reports-another-death>

See also:

Jan 18 FluTrackers post on [Wuhan confirmations for Jan 17](#)

Jan 19 FluTrackers post on [Wuhan confirmations for Jan 18 and 19](#)

Jan 19 FluTrackers post on [Shenzhen case](#)

Jan 18 WHO WPRO [Twitter thread](#) Jan 17 [Imperial College London report](#)

Jan 17 CIDRAP News story "[As Thailand notes 2nd nCoV case, CDC begins airport screening](#)"

Clark Tibbs, CEO

PhageVax, Inc. <https://protect2.fireeye.com/url?k=a798b82c-fbcca150-a7988913-0cc47adc5fa2-5f1f15814ace3f8a&u=http://www.phagevax.com/>

CAGE CODE: 4M4V6 www.sam.gov

Phone: 740.366.9013 Fax: 740.366.5230 Cell: (b)(6)

E-mail: Clark@PhageVax.com -or- PhageVax@roadrunner.com -or- CTA@ee.net

General Offices &HQ: 855 Sharon Valley Road, Suite 101 Newark, Ohio 43055-2860 USA

[(c) Statutory Copyright 2006-2020 - All Rights Reserved] This message is confidential and is PhageVax, Inc. legally privileged. If you are not the intended recipient, you should not disclose, copy or use any part of it - then delete all copies immediately & notify PVI, Inc. by replying to this email. Any information contained in this message (including any attachments) is given by the author. They are not given on behalf of PVI, Inc. unless subsequently confirmed by PVI, Inc.

Sender:	Clark Tibbs PhageVax-VHO < PhageVax@roadrunner.com >
Recipient:	Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>; Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>; Armstrong, Kimberly (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbac4d3ed652c-Armstrong,>; 'Gay, Cyril' < cyril.gay@usda.gov >; 'Gay, Cyril' < Cyril.Gay@ARS.USDA.GOV >; (b)(6); (b)(6); (b)(6); < stephen.leppia@nih.gov >; Adhya, Sankar (NIH/NCI) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fec05934ed0f42d6a24ccb8d19e1c6e5-sankar.adhy>; Biswajit Biswas PhD < biswas.biswajit.ctr@mail.mil >; 'Carl Merrill' <(b)(6)>; < robert.bonomo@va.gov >; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Khanna, Gopal (AHRQ/IOD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76eaf1c03eb347608851b240d65e1197-Khanna, Gop>; Meyers, David (AHRQ/IOD) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efa09be51c1b409f9bd6cbfa4b25a7f7-Meyers, Dav>; < Rachel.Ramoni@va.gov >; < MARISUE.CODY@VA.GOV >; (b)(6); (b)(6); (b)(6);
Sent Date:	2020/01/19 19:30:56
Delivered Date:	2020/01/19 19:31:40

From:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	To Dr. KADLEC at HHS :: T-4 Lambda Phage Head Vaccine Platform for > China releases genetic data on [2019-nCoV] ... Jan 11, 2020 ... Today is Jan 19
Date:	2020/01/19 20:46:01
Priority:	Normal
Type:	Note

Hello Dr. Kadlec,

Would you like to use **BARDA Emergency Funds** to finance several Vaccine Candidates vs. this 2019-nCoV ?

Please let me know? I know three (3) of the Authors who made this attached vaccine.

Clark Tibbs (b)(6)

From: Clark Tibbs PhageVax-VHO [mailto:PhageVax@roadrunner.com]
Sent: Saturday, January 11, 2020 5:04 PM
To: (b)(6); (b)(6)
Subject: To Drs. Chopra & Rao China releases genetic data on new coronavirus, now deadly via CIDRAP ... Jan 11, 2020

Gentlemen, I hope you will use the T-4 Phage Head Platform for this. Do you need funding ?? Good luck, Clark

=====

AT <https://protect2.fireeye.com/url?k=143de80c-4869c127-143dd933-0cc47a6d17cc-2ff7d8c2941c500b&u=http://virological.org/> ...

then click on <https://protect2.fireeye.com/url?k=6ed27c38-32865513-6ed24d07-0cc47a6d17cc-9fc9e93be421f7e2&u=http://virological.org/t/initial-genome-release-of-novel-coronavirus/319>

Initial genome release of novel coronavirus
Novel 2019 coronavirus

You have selected **0** posts.

[select all](#)

[cancel selecting](#)



http://virological.org/user_avatar/virological.org/arambaut/45/425_2.png
arambaut ARTIC Network

2
21h

10th January 2020

This posting is communicated by Edward C. Holmes, University of Sydney on behalf of the consortium led by Professor Yong-Zhen Zhang, Fudan University, Shanghai

The Shanghai Public Health Clinical Center & School of Public Health, in collaboration with the Central Hospital of Wuhan, Huazhong University of Science and Technology, the Wuhan Center for Disease Control and Prevention, the National Institute for Communicable Disease Control and Prevention, Chinese Center for Disease Control, and the University of Sydney, Sydney, Australia is releasing a coronavirus genome from a case of a respiratory disease from the Wuhan outbreak. The sequence has also been deposited on GenBank (accession MN908947) and will be released as soon as possible.

The sequence can be downloaded here:

WH-Human_1.fasta.gz (8.9 KB – this is a fasta file compressed using gzip. Uncompress using `gzip -d WH-Human_1.fasta.gz`)

Disclaimer:

Please feel free to download, share, use, and analyze this data. We ask that you communicate with us if you wish to publish results that use these data in a journal. If you have any other questions –then please also contact us directly.

Professor Yong-Zhen Zhang,
Shanghai Public Health Clinical Center & School of Public Health,
Fudan University,
Shanghai, China.

zhangyongzhen@shphc.org.cn

=====

Below is from:

<http://www.cidrap.umn.edu/news-perspective/2020/01/china-releases-genetic-data-new-coronavirus-now-deadly>

China releases genetic data on new coronavirus, now deadly ... Jan 11, 2020

In quickly moving developments last night, health officials from Wuhan, China, posted a novel coronavirus (nCoV) pneumonia outbreak update, which scaled back the number of cases to 41

and **noted the first death**, and researchers from China released the genetic sequence of the nCoV.

And this morning the World Health Organization (WHO) released several interim guidance documents, including advice on travel, lab testing, and medical evaluation.

Michael T. Osterholm, PhD, MPH, said he's pleased to see that health officials and scientists in China have released as much information as they have. He said the main focus now turns toward identifying the animal species that transmitted nCoV to humans and determining whether exposure to those animals poses a threat of outbreaks in other areas.

Osterholm is director of the University of Minnesota's Center for Infectious Disease Research and Policy, which publishes CIDRAP News.

No sign of human-to-human spread

Based on the current reports, there's no obvious evidence of human-to-human spread yet, Osterholm said, noting that red flags, for example, would be infections in patients' family members who weren't at the market and infections in healthcare workers.

The outbreak update posted last night by Wuhan's health commission was its first since Jan 5. The report was quickly translated and posted by FluTrackers, an infectious disease news message board, and the details also appeared in an English language statement from Hong Kong's Centre for Health Protection (CHP).

Wuhan officials said 41 patients have been diagnosed with nCoV pneumonia, and 2 have been discharged from the hospital. Seven had severe infections, and 1 patient died. The rest are listed in stable condition.

The patient who died is apparently a 61-year-old man who had chronic liver disease and was a frequent customer at the market at the center of the investigation, according to a translation of a Chinese media report posted on Twitter by Hayes Luk, PhD, a microbiologist at the University of Hong Kong.

So far 739 close contacts have been identified for monitoring, 419 of them medical staff. No related cases have been detected.

Investigators haven't found any clear evidence of human-to-human spread, and no infections have been found in healthcare workers. Most of the patients were workers at the **seafood market** at the center of the outbreak, which also sold **live animals** and **meat** from **wildlife**. The most recent illness was reported on Jan 3.

Genetic findings, search for more clues

Chinese scientists submitted the gene sequencing data for posting on ...

[https://protect2.fireeye.com/url?k=55f4a8ea-09a081c1-55f499d5-0cc47a6d17cc-](https://protect2.fireeye.com/url?k=55f4a8ea-09a081c1-55f499d5-0cc47a6d17cc-019a921cc47e57ea&u=http://www.virological.org/)

[019a921cc47e57ea&u=http://www.virological.org/](https://protect2.fireeye.com/url?k=55f4a8ea-09a081c1-55f499d5-0cc47a6d17cc-019a921cc47e57ea&u=http://www.virological.org/) ... a hub for prepublication data designed to assist with public health activities and research. Earlier this week, they announced that they had

isolated and fully sequenced the virus, setting off calls for full release of the details. The post was communicated by Edward Holmes, PhD, with the University of Sydney, on behalf of a Chinese group led by Yong-Zhen Zhang, PhD, with Fudan University in Shanghai.

Since the release of the gene sequences, coronavirus experts have been pouring over them looking for clues on where the Wuhan nCoV came from, how lab officials might test for it, and how it might behave.

Vineet Menachery, PhD, with the University of Texas Medical Branch (UTMB) said on Twitter that nCoV appears to be a group 2B coronavirus, which puts it in the same family as the SARS (severe acute respiratory syndrome) virus.

Andrew Rambaut, PhD, administrator of Virological.org and professor of molecular evolution at the University of Edinburgh, said on Twitter that nCoV is 89% similar to SARS-related bat coronavirus in the *Sarbecovirus* group of betacoronaviruses. "But that doesn't mean it comes from bats. MERS-CoV is 88% identical to the nearest known bat virus, and MERS is endemic in camels."

He said though bat viruses span coronavirus diversity and bats are a dominant host in much of the evolutionary history, the link to bats was a distraction when looking for the source of human MERS-CoV (Middle East respiratory syndrome coronavirus) cases.

Another question that the gene sequences could shed light on is the size of the animal source population, Rambaut said. For example, if the 10 genomes so far are nearly identical, then all patients were probably exposed to the same few animals.

Regarding early prospects for testing, **Menachery** noted that the nucleocapsid protein for coronaviruses is highly conserved across coronavirus families, and the N protein of nCoV is about 90% conserved with the SARS N protein. Though less than some other coronaviruses, the similarity may signal nCoV cross-reactivity with the SARS N protein. If there is cross-reactivity, commercially available SARS N protein might allow screening of patient sera.

In a follow-up, **Menachery** said testing for the antibody for the N protein may be effective, but it would need to be tested and verified. Though it's not clear if there are commercial tests that look for the N protein, the N protein is available and could be used to look for exposure in human blood samples. "It is not as good as making N protein specific to the new virus, but a quick and dirty way to test for exposure," he said.

WHO travel, medical guidance

This morning the WHO on Twitter acknowledged the new information from Wuhan health officials and added that Chinese authorities narrowed the number of cases from the earlier 59 illnesses with the use of a genomic test kit.

It also provided preliminary guidance to help countries prepare for nCoV cases, including travel and trade advice. The WHO urges international travelers to practice usual precautions and calls for no restriction on international travel.

On its coronavirus page, the agency posted several interim technical documents for nCoV, which cover the case definition, laboratory guidance, infection prevention and control, risk communications, a readiness checklist, and a disease commodity package.

See also:

Virological.net [post](#)

Clark Tibbs, CEO

PhageVax, Inc.

<https://protect2.fireeye.com/url?k=cb49f5b9-971ddc92-cb49c486-0cc47a6d17cc-ce342f780df4a1d4&u=http://www.phagevax.com/>

CAGE CODE: 4M4V6 www.sam.gov

Phone: 740.366.9013 Fax: 740.366.5230 Cell: (b)(6)

E-mail: Clark@PhageVax.com -or- PhageVax@roadrunner.com -or- CTA@ee.net

General Offices &HQ: 855 Sharon Valley Road, Suite 101 Newark, Ohio 43055-2860 USA

[(c) Statutory Copyright 2006-2020 - All Rights Reserved] This message is confidential and is PhageVax, Inc. legally privileged. If you are not the intended recipient, you should not disclose, copy or use any part of it - then delete all copies immediately & notify PVI, Inc. by replying to this email. Any information contained in this message (including any attachments) is given by the author. They are not given on behalf of PVI, Inc. unless subsequently confirmed by PVI, Inc.

Sender:	Clark Tibbs PhageVax-VHO < PhageVax@roadrunner.com >
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/01/19 20:43:37
Delivered Date:	2020/01/19 20:46:01

From:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
To:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
Subject:	Read: To Dr. KADLEC at HHS :: T-4 Lambda Phage Head Vaccine Platform for > China releases genetic data on [2019-nCoV] ... Jan 11, 2020 ... Today is Jan 19
Date:	2020/01/19 20:46:16
Priority:	Normal
Type:	REPORT.IPM.Note.IPNRN

Sender:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
Recipient:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
Sent Date:	2020/01/19 20:46:16

From:	Moreno, Rafael (OS/ASPR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1DCC2DA7031645B39C430A140FD4C446-MORENO, RAF>
To:	Imbriale, Samuel (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7e54524>
CC:	Phillips, Sally (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Moreno, Rafael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dcc2da7031645b39c430a140fd4c446-Moreno, Raf>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>
Subject:	RE: Suggested Kadlec TPs for SOC All Hands
Date:	2020/01/19 21:43:05
Priority:	Normal
Type:	Note

Hello Sam,

These past few weeks have been quite hectic. With the events in PR, Middle East and Novel Coronavirus staff have been stretched. Do you have 1 or 2 staff that have stood out throughout these past few weeks? I am thinking that the all hands may be a good venue for the boss to present an ASPR lapel pin to them. Your thoughts?

V/r

Rafael Moreno III

Special Assistant to the ASPR

Immediate Office, Assistant Secretary for Preparedness and Response (ASPR)

US Dept. Health and Human Services (HHS)

Desk: (202) 260-1042

Cell: (b)(6)

rafael.moreno@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>

Sent: Sunday, January 19, 2020 11:04 AM

To: Imbriale, Samuel (OS/ASPR/SIIM) <Samuel.Imbriale@hhs.gov>

Cc: Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Ford-Barnes, Arwenithia (OS/ASPR/IO) <Arwenithia.FordBarnes@hhs.gov>; Moreno, Rafael (OS/ASPR) <Rafael.Moreno@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>

Subject: RE: Suggested Kadlec TPs for SOC All Hands

Thanks Sam very helpful .

From: Imbriale, Samuel (OS/ASPR/SIIM) <Samuel.Imbriale@hhs.gov>

Sent: Sunday, January 19, 2020 11:02 AM

To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>

Cc: Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov>; Moreno, Rafael (OS/ASPR) <Rafael.Moreno@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>

Subject: Suggested Kadlec TPs for SOC All Hands

Suggested talking points below – use as you see fit:

(b)(5)

(b)(5)

V/r,

Samuel Imbriale, MPH

Director, Information Management Division

Director (Acting), Secretary's Operations Center

Office of Security, Intelligence & Information Management

Assistant Secretary for Preparedness & Response

Office: (202) 205-2843

Cell: (b)(6)

Email: Samuel.Imbriale@hhs.gov

HSDN: Samuel.m.imbriale@dhs.sgov.gov

Sender:	Moreno, Rafael (OS/ASPR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1DCC2DA7031645B39C430A140FD4C446-MORENO, RAF>
Recipient:	Imbriale, Samuel (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7e54524>; Phillips, Sally (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Moreno, Rafael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dcc2da7031645b39c430a140fd4c446-Moreno, Raf>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>
Sent Date:	2020/01/19 21:43:03
Delivered Date:	2020/01/19 21:43:05

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 20Jan20
Date:	2020/01/20 06:45:17
Priority:	Normal
Type:	Note

HHS Executive Summary: Monday, 20Jan20

1. HHS

Today's Noteworthy Topics:

Novel Coronavirus, Wuhan, China

On 19Jan20, Wuhan Municipal Health Commission reported that on 18Jan20, 59 cases were newly added and 1 patient died. To date, 198 cases of pneumonia with 2019 nCoV have been reported in Wuhan, 170 cases are still being treated in the hospital, 126 of whom are considered mild, 35 are severe, and 9 cases are critically ill. There has been one more incident death for a total of 3 deaths. Onset dates of illness were before 18Jan20. Over 817 close contacts have been traced, including over 400 medical staff, 727 medical observations have been lifted, and 90 are still under medical observation. Three reports of cases reported outside of Wuhan: two in Beijing and one in Guangdong Province. San Francisco (SFO), Los Angeles (LAX) and John F Kennedy (JFK) airports are conducting entry screening of travelers arriving from Wuhan, 731 persons were screened as of 18Jan20 and none were referred for medical evaluation. Wuhan City is undertaking additional control efforts. Wuhan is strengthening temperature screening at airport, railway station, long distance bus station and ferry terminals, All live animal sales are prohibited. Screening is being done in the 72 "fever clinics" in the city where 2000 fever patients are seen daily.

Daily Operational Schedule: NSTR

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19

Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level IV (Steady State)

CDC EOC: Level III (Polio/Ebola/Lung Injury)

FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 05Mar20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 88)

ASPR: 11 – (3) Irma/Maria, (1) 2018 California Wildfires, (7) 2020 Earthquake Puerto Rico
CDC: 77 – (25) Polio, (50) Ebola, (2) Puerto Rico

FMS Status:

- • 32 (250 Bed) FMS sets are deployable
- • 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR

Active Situations (7):

- • Influenza Season
- • Irma/Maria, Puerto Rico, &USVI (Recovery)
- • Ebola in Eastern Democratic Republic of the Congo
- • California Wildfires (Recovery)
- Novel Coronavirus, China
- Bravo Response
- Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: Monitoring

NRCC: Blue

National IMATs: Red – Fully Mission Capable; Blue – Deployed – PR; Gold – Demobilizing

Regional IMATs: Region I, Demobilizing; Region II, PR; Region VIII, SD

Significant National Weather:

Heavy rain and thunderstorms possible for portions of southern FL and coastal NC. Freezing rain forecast for the Cascade mountains of WA and OR. Expansive Canadian-sourced high pressure will provide mainly fair weather across the U.S. on Monday. Temperatures over the eastern states will run below normal while the western states see above normal temperatures but no records are expected to fall. On Monday night, a cold front will move onshore in the Pacific Northwest bringing low elevation rain and mountain snow.

3. OPDIV/STAFFDIV Overnight Reports:

CDC: NSTR

FDA: NSTR

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)

Assistant Secretary for Preparedness and Response (ASPR)

200 Independence Ave., S.W.

Washington, D.C. 20201

Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/20 06:45:11
Delivered Date:	2020/01/20 06:45:17

From:	Mike Allen <mike@axios.com>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	Axios AM: Mike's Great 8 — The next global crisis — Bracing for hate — Super Bowl odds
Date:	2020/01/20 07:55:05
Priority:	Normal
Type:	Note



Good Monday morning. Faith, politics and history will combine today as America celebrates

⚡ **Breaking:** China's coronavirus spread to South Korea after a resident of Wuhan flew to Seoul

• • **"More than 200 people** have been confirmed as suffering from the new virus that br

1 big thing: Global trust crisis



Sender:	Mike Allen <mike@axios.com>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/01/20 07:54:19
Delivered Date:	2020/01/20 07:55:05

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1DCC2DA7031645B39C430A140FD4C446-MORENO, RAF>
To:	Imbriale, Samuel (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7e54524>
CC:	Phillips, Sally (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>
Subject:	Re: Suggested Kadlec TPs for SOC All Hands
Date:	2020/01/20 08:45:08
Priority:	Normal
Type:	Note

Hey Sam,

Totally ok if they are not in-person. We can make a honorable mention and when they are in town we can make some time for the boss to present it to them.

If you would like to do it just provide us with their name, 3 or 4 lines of some of the work they have done to get them the ASPR lapel pin.

Rafael

Sent from my iPhone

On Jan 20, 2020, at 7:59 AM, Imbriale, Samuel (OS/ASPR/SIIM)
<Samuel.Imbriale@hhs.gov>wrote:

Raphael, a good idea but a couple challenges.

(b)(5)

Sam

V/r,

Sam Imbriale, MPH

Director, Information Management Division
Director (Acting), Secretary's Operations Center
Cell: (b)(6)
Samuel.imbriale@hhs.gov
Sent from mobile device - please excuse typos.

On: 19 January 2020 21:43,
"Moreno, Rafael (OS/ASPR)" <Rafael.Moreno@hhs.gov> wrote:

Hello Sam,

These past few weeks have been quite hectic. With the events in PR, Middle East and Novel Coronavirus staff have been stretched. Do you have 1 or 2 staff that have stood out throughout these past few weeks? I am thinking that the all hands may be a good venue for the boss to present an ASPR lapel pin to them. Your thoughts?

V/r

Rafael Moreno III

Special Assistant to the ASPR
Immediate Office, Assistant Secretary for Preparedness and Response (ASPR)
US Dept. Health and Human Services (HHS)
Desk: (202) 260-1042
Cell: (b)(6)
rafael.moreno@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Sunday, January 19, 2020 11:04 AM
To: Imbriale, Samuel (OS/ASPR/SIIM) <Samuel.Imbriale@hhs.gov>
Cc: Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Ford-Barnes, Arwenethia (OS/ASPR/IO) <Arwenethia.FordBarnes@hhs.gov>; Moreno, Rafael (OS/ASPR) <Rafael.Moreno@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: RE: Suggested Kadlec TPs for SOC All Hands

Thanks Sam very helpful .

From: Imbriale, Samuel (OS/ASPR/SIIM) <Samuel.Imbriale@hhs.gov>
Sent: Sunday, January 19, 2020 11:02 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Ford-Barnes, Arwenethia (OS/ASPR/IO)

<Arwenthia.FordBarnes@hhs.gov>; Moreno, Rafael (OS/ASPR) <Rafael.Moreno@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>

Subject: Suggested Kadlec TPs for SOC All Hands

Suggested talking points below – use as you see fit:

(b)(5)

V/r,

Samuel Imbriale, MPH

Director, Information Management Division

Director (Acting), Secretary's Operations Center

Office of Security, Intelligence & Information Management

Assistant Secretary for Preparedness & Response

Office: (202) 205-2843

Cell: (b)(6)

Email: Samuel.Imbriale@hhs.gov

HSDN: Samuel.m.imbriale@dhs.sgov.gov

Sender:	Moreno, Rafael (OS/ASPR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1DCC2DA7031645B39C430A140FD4C446-MORENO, RAF>
Recipient:	Imbriale, Samuel (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7e54524>; Phillips, Sally (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>
Sent Date:	2020/01/20 08:45:05
Delivered Date:	2020/01/20 08:45:08

From:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
To:	'Carl Merrill' (b)(6) >; Biswajit Biswas PhD <biswas.biswajit.ctr@mail.mil>; <stephen.leppla@nih.gov>; (b)(6) >; (b)(6) >; Adhya, Sankar (NIH/NCI) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fec05934ed0f42d6a24ccb8d19e1c6e5-sankar.adhy>
CC:	<robert.bonomo@va.gov>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Armstrong, Kimberly (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong,>; <Rachel.Ramoni@va.gov>; <MARISUE.CODY@VA.GOV>; (b)(6) >; (b)(6) >; (b)(6) >; Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>; Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>
Subject:	TO Drs. MERRIL & BISWAS & Others :: T-4 Lambda Phage Head Vaccine Platform vs. 2019-nCoV Virus ... [Sequence online Jan 11, 2020] ... Today is Jan 20
Date:	2020/01/20 12:08:15
Priority:	Normal
Type:	Note

Would you like to use **US NAVY Emergency Funds** to finance several Vaccine Candidates vs. this 2019-nCoV ?

See this Attachment, *please* ... The funding, of course, would go to these Authors.

Please let me know, soon, otherwise, I will have to pursue other funding avenues. Clark Tibbs (b)(6)

From: Clark Tibbs PhageVax-VHO [mailto:PhageVax@roadrunner.com]
Sent: Sunday, January 19, 2020 8:44 PM
To: 'Robert.Kadlec@hhs.gov'
Subject: To Dr. KADLEC at HHS :: T-4 Lambda Phage Head Vaccine Platform for >China releases genetic data on [2019-nCoV] ... Jan 11, 2020 ... Today is Jan 19

Hello Dr. Kadlec,

Would you like to use **BARDA Emergency Funds** to finance several Vaccine Candidates vs. this 2019-nCoV ?

Please let me know? I know three (3) of the Authors who made this attached vaccine.

Clark Tibbs 1-740-366-9013

From: Clark Tibbs PhageVax-VHO [mailto:PhageVax@roadrunner.com]
Sent: Saturday, January 11, 2020 5:04 PM
To: 'achopra@UTMB.EDU'; 'rao@cua.edu'
Subject: To Drs. Chopra & Rao China releases genetic data on new coronavirus, now deadly via CIDRAP ... Jan 11, 2020

Gentlemen, I hope you will use the T-4 Phage Head Platform for this. Do you need funding ?? Good luck, Clark

=====

AT <https://protect2.fireeye.com/url?k=9be7bf6d-c7b2b67e-9be78e52-0cc47adb5650-2e44b548b7d0ee02&u=http://virological.org/> ...

then click on <https://protect2.fireeye.com/url?k=a592a825-f9c7a136-a592991a-0cc47adb5650-bced428a882175bd&u=http://virological.org/t/initial-genome-release-of-novel-coronavirus/319>

Initial genome release of novel coronavirus **Novel 2019 coronavirus**

You have selected 0 posts.

[select all](#)

[cancel selecting](#)



http://virological.org/user_avatar/virological.org/arambaut/45/425_2.png
[arambaut](#) ARTIC Network
[2](#)
[21h](#)

10th January 2020

This posting is communicated by Edward C. Holmes, University of Sydney on behalf of the consortium led by Professor Yong-Zhen Zhang, Fudan University, Shanghai

The Shanghai Public Health Clinical Center & School of Public Health, in collaboration with the Central Hospital of Wuhan, Huazhong University of Science and Technology, the Wuhan Center for Disease Control and Prevention, the National Institute for Communicable Disease Control and Prevention, Chinese Center for Disease Control, and the University of Sydney, Sydney, Australia is releasing a coronavirus genome from a case of a respiratory disease from the Wuhan outbreak. The sequence has also been deposited on [GenBank \(accession MN908947\)](#) and will be released as soon as possible.

The sequence can be downloaded here:

WH-Human_1.fasta.gz (8.9 KB – this is a fasta file compressed using gzip. Uncompress using `gzip -d WH-Human_1.fasta.gz`)

Disclaimer:

Please feel free to download, share, use, and analyze this data. We ask that you communicate with us if you wish to publish results that use these data in a journal. If you have any other questions –then please also contact us directly.

Professor Yong-Zhen Zhang,
Shanghai Public Health Clinical Center & School of Public Health,
Fudan University,
Shanghai, China.

zhangyongzhen@shphc.org.cn

=====

Below is from:

<http://www.cidrap.umn.edu/news-perspective/2020/01/china-releases-genetic-data-new-coronavirus-now-deadly>

China releases genetic data on new coronavirus, now deadly ... Jan 11, 2020

In quickly moving developments last night, health officials from Wuhan, China, posted a novel coronavirus (nCoV) pneumonia outbreak update, which scaled back the number of cases to 41 and **noted the first death**, and researchers from China released the genetic sequence of the nCoV.

And this morning the World Health Organization (WHO) released several interim guidance documents, including advice on travel, lab testing, and medical evaluation.

Michael T. Osterholm, PhD, MPH, said he's pleased to see that health officials and scientists in China have released as much information as they have. He said the main focus now turns toward identifying the animal species that transmitted nCoV to humans and determining whether exposure to those animals poses a threat of outbreaks in other areas.

Osterholm is director of the University of Minnesota's Center for Infectious Disease Research and Policy, which publishes CIDRAP News.

No sign of human-to-human spread

Based on the current reports, there's no obvious evidence of human-to-human spread yet, Osterholm said, noting that red flags, for example, would be infections in patients' family members who weren't at the market and infections in healthcare workers.

The outbreak update posted last night by Wuhan's health commission was its first since Jan 5. The report was quickly translated and posted by FluTrackers, an infectious disease news message

board, and the details also appeared in an English language statement from Hong Kong's Centre for Health Protection (CHP).

Wuhan officials said 41 patients have been diagnosed with nCoV pneumonia, and 2 have been discharged from the hospital. Seven had severe infections, and 1 patient died. The rest are listed in stable condition.

The patient who died is apparently a 61-year-old man who had chronic liver disease and was a frequent customer at the market at the center of the investigation, according to a translation of a Chinese media report posted on Twitter by Hayes Luk, PhD, a microbiologist at the University of Hong Kong.

So far 739 close contacts have been identified for monitoring, 419 of them medical staff. No related cases have been detected.

Investigators haven't found any clear evidence of human-to-human spread, and no infections have been found in healthcare workers. Most of the patients were workers at the **seafood market** at the center of the outbreak, which also sold **life animals** and **meat** from **wildlife**. The most recent illness was reported on Jan 3.

Genetic findings, search for more clues

Chinese scientists submitted the gene sequencing data for posting on ...

<https://protect2.fireeye.com/url?k=1eed1c6-42bbd8d5-1eeee0f9-0cc47adb5650-489f89b515c2a7ab&u=http://www.virological.org/> ... a hub for prepublication data designed to assist with public health activities and research. Earlier this week, they announced that they had isolated and fully sequenced the virus, setting off calls for full release of the details. The post was communicated by Edward Holmes, PhD, with the University of Sydney, on behalf of a Chinese group led by Yong-Zhen Zhang, PhD, with Fudan University in Shanghai.

Since the release of the gene sequences, coronavirus experts have been pouring over them looking for clues on where the Wuhan nCoV came from, how lab officials might test for it, and how it might behave.

Vineet Menachery, PhD, with the University of Texas Medical Branch (UTMB) said on Twitter that nCoV appears to be a group 2B coronavirus, which puts it in the same family as the SARS (severe acute respiratory syndrome) virus.

Andrew Rambaut, PhD, administrator of Virological.org and professor of molecular evolution at the University of Edinburgh, said on Twitter that nCoV is 89% similar to SARS-related bat coronavirus in the *Sarbecovirus* group of betacoronaviruses. "But that doesn't mean it comes from bats. MERS-CoV is 88% identical to the nearest known bat virus, and MERS is endemic in camels."

He said though bat viruses span coronavirus diversity and bats are a dominant host in much of the evolutionary history, the link to bats was a distraction when looking for the source of human MERS-CoV (Middle East respiratory syndrome coronavirus) cases.

Another question that the gene sequences could shed light on is the size of the animal source population, Rambaut said. For example, if the 10 genomes so far are nearly identical, then all patients were probably exposed to the same few animals.

Regarding early prospects for testing, **Menachery** noted that the nucleocapsid protein for coronaviruses is highly conserved across coronavirus families, and the N protein of nCoV is about 90% conserved with the SARS N protein. Though less than some other coronaviruses, the similarity may signal nCoV cross-reactivity with the SARS N protein. If there is cross-reactivity, commercially available SARS N protein might allow screening of patient sera.

In a follow-up, **Menachery** said testing for the antibody for the N protein may be effective, but it would need to be tested and verified. Though it's not clear if there are commercial tests that look for the N protein, the N protein is available and could be used to look for exposure in human blood samples. "It is not as good as making N protein specific to the new virus, but a quick and dirty way to test for exposure," he said.

WHO travel, medical guidance

This morning the WHO on Twitter acknowledged the new information from Wuhan health officials and added that Chinese authorities narrowed the number of cases from the earlier 59 illnesses with the use of a genomic test kit.

It also provided preliminary guidance to help countries prepare for nCoV cases, including travel and trade advice. The WHO urges international travelers to practice usual precautions and calls for no restriction on international travel.

On its coronavirus page, the agency posted several interim technical documents for nCoV, which cover the case definition, laboratory guidance, infection prevention and control, risk communications, a readiness checklist, and a disease commodity package.

See also:

Virological.net post

Clark Tibbs, CEO
PhageVax, Inc. <https://protect2.fireeye.com/url?k=6498626a-38cd6b79-64985355-0cc47adb5650-ae039a956c6f15aa&u=http://www.phagevax.com/>
CAGE CODE: 4M4V6 www.sam.gov

Phone: 740.366.9013 Fax: 740.366.5230 Cell: 740.502.9010

E-mail: Clark@PhageVax.com -or- PhageVax@roadrunner.com -or- CTA@ee.net

General Offices & HQ: 855 Sharon Valley Road, Suite 101 Newark, Ohio 43055-2860 USA

[(c) Statutory Copyright 2006-2020 - All Rights Reserved] This message is confidential and is PhageVax, Inc. legally privileged. If you are not the intended recipient, you should not disclose, copy or use any part of it - then delete all copies immediately & notify PVI, Inc. by replying to this email. Any information contained in this message (including any attachments) is given by the author. They are not given on behalf of PVI, Inc. unless subsequently confirmed by PVI, Inc.

-

Sender:	Clark Tibbs PhageVax-VHO < PhageVax@roadrunner.com >
Recipient:	'Carl Merrill' (b)(6); Biswajit Biswas PhD < biswas.biswajit.ctr@mail.mil >;

<stephen.leppla@nih.gov>;

(b)(6)

(b)(6)

Adhya, Sankar (NIH/NCI) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fec05934ed0f42d6a24ccb8d19e1c6e5-sankar.adhy>;

<robert.bonomo@va.gov>;

Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>;

Armstrong, Kimberly (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong,>;

<Rachel.Ramoni@va.gov>;

<MARISUE.CODY@VA.GOV>;

(b)(6)

(b)(6)

(b)(6)

Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>;

Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>

Sent Date: 2020/01/20 12:06:34

Delivered Date: 2020/01/20 12:08:15

From:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
To:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
Subject:	Read: TO Drs. MERRIL & BISWAS & Others :: T-4 Lambda Phage Head Vaccine Platform vs. 2019-nCoV Virus ... [Sequence online Jan 11, 2020] ... Today is Jan 20
Date:	2020/01/20 13:54:26
Priority:	Normal
Type:	REPORT.IPM.Note.IPNRN

Sender:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
Recipient:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
Sent Date:	2020/01/20 13:54:26

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.YDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; McGowan, Robert (Kyle) (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2046e75239f48a28d2854bedbe5f899-robert.mcgo>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Grigsby, Garrett (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd78b4810d44b17b8711aaede9a9023-Grigsby, Gl>
Subject:	Fwd: WHO prepares to take action against deadly Chinese virus
Date:	2020/01/20 14:12:39
Priority:	Normal
Type:	Note

Sent from my iPhone

Begin forwarded message:

From: "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>
Date: January 20, 2020 at 2:02:58 PM EST
To: "Hall, Bill (HHS/ASPA)" <bill.hall@hhs.gov>, "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>, "Oakley, Caitlin B. (OS/ASPA)" <Caitlin.Oakley@HHS.GOV>, "McKeogh, Katherine (OS/ASPA)" <Katherine.McKeogh@hhs.gov>
Subject: FW: WHO prepares to take action against deadly Chinese virus

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Monday, January 20, 2020 1:50 PM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Subject: WHO prepares to take action against deadly Chinese virus

WHO prepares to take action against deadly Chinese virus

By Arthur Allen

01/20/2020 01:48 PM EST

A World Health Organization committee will meet Wednesday to decide whether to declare an international emergency over a new virus that has swept into major Chinese cities and three other

countries.

The virus has sickened over 200 people and claimed three lives, according to Chinese authorities. The virus, first reported in the city of Wuhan in late December, has been detected in Beijing, Shanghai, Shenzhen and other cities, according to news reports. There is concern it could spread widely as people travel to visit relatives for Saturday's Chinese New Year.

The coronavirus causing the disease is the same general type that caused the severe acute respiratory syndrome, or SARS, in 2003, as well as some forms of the common cold.

U.S. authorities on Friday began screening travelers arriving at San Francisco, New York and Los Angeles airports from Wuhan or connecting cities.

The WHO committee, convened by Director-General Tedros Adhanom Ghebreyesus, will decide whether the outbreak constitutes a global emergency and what should be done about it, according to WHO spokesperson Tarik Jasarevic. Under a 2005 agreement following the SARS epidemic, the committee can issue recommendations to more than 190 member states.

Scientific authorities told China Central Television today that there had been at least two human-to-human transmissions of the virus. And a 35-year-old woman visiting South Korea was confirmed to have a case. The virus has also been detected in Thailand and Japan.

Chinese President Xi Jinping urged authorities today to release information quickly and to expand international cooperation to stop the virus' spread, according to news reports from Beijing.

To view online:

<https://protect2.fireeye.com/url?k=b973a1b1-e527889a-b973908e-0cc47a6d17cc-a98b1f95f1389e6b&u=https://subscriber.politicopro.com/health-care/whiteboard/2020/01/who-prepares-to-take-action-against-deadly-chinese-virus-3975838>

You received this POLITICO Pro content because your customized settings include: Diseases and Conditions, Infectious Diseases. To change your alert settings, please go to <https://protect2.fireeye.com/url?k=2f724b18-73266233-2f727a27-0cc47a6d17cc-2286690a0be2eedc&u=https://subscriber.politicopro.com/settings>.

POLITICOPRO

This email alert has been sent for the exclusive use of POLITICO Pro subscriber, ryan.murphy1@hhs.gov. Forwarding or reproducing the alert without the express, written permission of POLITICO Pro is a violation of copyright law and the POLITICO Pro subscription agreement.

Copyright © 2020 by POLITICO LLC. To subscribe to Pro, please go to politicopro.com.

This email was sent to ryan.murphy1@hhs.gov by:
POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA

Sender:	Stecker, Judy (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; McGowan, Robert (Kyle) (CDC/OD/OCS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2046e75239f48a28d2854bedbe5f899-robert.mcgo>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Grigsby, Garrett (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd78b4810d44b17b8711aaede9a9023-Grigsby, GI>
Sent Date:	2020/01/20 14:12:37
Delivered Date:	2020/01/20 14:12:39

From:	WHO Event Information Site <outbreak@who.int>
SentVia:	<outbreak@who.int>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	WHO Event Information Site - New Announcement
Date:	2020/01/20 15:05:19
Priority:	Normal
Type:	Note

Dear Colleagues,

Please note for your information that the Event Information Site has been updated.
URL: <https://extranet.who.int/ihr/eventinformation>

New announcement:

Meeting of the International Health Regulations (IHR) Emergency Committee for pneumonia due to the novel coronavirus 2019_nCoV convened by the WHO Director-General on 22 January 2020

Kind regards,

Detection, Verification and Risk Assessment
Health Emergency Information and Risk Assessment
WHO Health Emergencies Programme

World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland
Email: outbreak@who.int

Sender:	WHO Event Information Site <outbreak@who.int>; <outbreak@who.int>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/01/20 15:05:08
Delivered Date:	2020/01/20 15:05:19

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.P (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USER57698E56>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Grigsby, Garrett (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd78b4810d44b17b8711aaede9a9023-Grigsby, Gl>
CC:	Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>
Subject:	Fwd: (U) WHO Calls For Emergency Meeting, Says 'Animal Source' Likely Primary Source Of Outbreak-MMC Update 8 [Novel Coronavirus - U.S.] NOC 0051-20
Date:	2020/01/20 15:53:30
Priority:	Normal
Type:	Note

Very respectfully,

Michael Schmoyer, Ph.D
National Security Advisor to the Secretary
Director, Office of National Security
CAPT, USPHS
SchmoyerM@HHS.ID.IC.GOV
VOIP: 936-2129

Begin forwarded message:

From: NOC Media Monitoring <mmc@techopsolutions.net>
Date: January 20, 2020 at 3:41:16 PM EST
To: "noc.mmc@hq.dhs.gov" <noc.mmc@hq.dhs.gov>
Subject: (U) WHO Calls For Emergency Meeting, Says 'Animal Source' Likely Primary Source Of Outbreak-MMC Update 8 [Novel Coronavirus - U.S.] NOC 0051-20

Unclassified

Location(s): China

- • The World Health Organization (WHO) called for an emergency meeting on Monday following the outbreak of the new coronavirus across China
 - • The meeting on Wednesday will assess whether the outbreak constitutes an international health emergency and what measures should be taken
- • The health organization said "an animal source" is likely to be the primary source of the outbreak, adding that some "limited human-to-human transmission" occurred between close contacts

- • The WHO has not yet recommended trade or travel restrictions
- • The virus, which was first discovered in Wuhan, has spread to more Chinese cities, including five confirmed cases in Beijing and one in Shanghai, authorities said Monday
- • The total number of cases across the world was reported at 221

New Media Sources (some page content may change or not be available over time):

- **Twitter [thehill]**

-- <https://tinyurl.com/spf2jab>

- **Reuters**

-- <https://protect2.fireeye.com/url?k=9e0650c0-c2535910-9e0661ff-0cc47a6a52de-bc8f3b93b4c05a4c&u=https://tinyurl.com/qp5jpuc>

The above information summarizes emerging open source reporting that has not been corroborated by official government sources. It is provided to rapidly enhance situational awareness on items of interest to the homeland security enterprise.

Nathan Doctor

Operations Analyst

DHS NOC Media Monitoring

Phone: 703-596-1015

Cell: (b)(6)

Unclassified

Sender:	Schmoyer, Michael (OS/ONS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USER57698E56>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Grigsby, Garrett (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cd78b4810d44b17b8711aaede9a9023-Grigsby, G>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>
Sent Date:	2020/01/20 15:53:29
Delivered Date:	2020/01/20 15:53:30

From:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
SentVia:	Ford-Barnes, Arwenithia (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D533ABC24CBE44B79F6FDDC6B08737A6-FORD-BARNES>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Waters, Cicely (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic>; Moreno, Rafael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dcc2da7031645b39c430a140fd4c446-Moreno, Raf>; Hassell, David (Chris) (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aedbf0ff96e4119ac7a3b3abaf71a3d-Hassell, Da>; Sauer, Michael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc2ae02156624623b24d3a400f592229-Sauer, Mich>; Callahan, Victoria (OS/ASPR/IO) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95162cb185624a6ebe5fadf08484c141-Callanhan,>; 'Carrie Bueche' <CBueche@cfr.org>
Subject:	Bio Security and World Health Discussion
Date:	2020/01/20 12:24:50
Start Date:	2020/02/18 12:00:00
End Date:	2020/02/18 13:30:00
Priority:	Normal
Type:	Appointment
Location:	CFR in DC located at 1777 F Street NW.

2/17/2020 at 8:30pm - Sir, the attachments came in from Fran Townsend today at 6:55pm

All: Below is an outline of questions for tomorrow at CFR. Sorry to get this to you late but it seems the news changes everyday. As you will see I focus mostly on coronavirus as I suspect that's where the interest will be but get to bio weapons toward the end.

I am happy to take additional questions or suggestions. These sessions go quickly and we have time for Q and A so I doubt I will get through it all but wanted you all to have something to look at.

Thanks again for doing this tomorrow.

Best

Fran

From: Carrie Bueche <CBueche@cfr.org>

Sent: Wednesday, February 5, 2020 12:47 PM

To: Ford-Barnes, Arwenithia (OS/ASPR/IO) <Arwenithia.FordBarnes@hhs.gov>

Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Callahan, Victoria (OS/ASPR/IO) (CTR)

<Victoria.Callahan@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>

Subject: RE: Bio Security and World Health

Dear Arwenithia,

Please find attached a confirmation packet for Dr. Kadlec that includes a detailed timeline of the CFR event on February 18. I've also attached a list of registered audience members for his reference. I'll be in touch with more details soon, but please let me know if you or Dr. Kadlec have any questions about the event.

All best,
Carrie

Sender:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D533ABC24CBE44B79F6FDDC6B08737A6-FORD-BARNES>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Waters, Cicely (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic>; Moreno, Rafael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dcc2da7031645b39c430a140fd4c446-Moreno, Raf>; Hassell, David (Chris) (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aedbf0ff96e4119ac7a3b3abaf71a3d-Hassell, Da>; Sauer, Michael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc2ae02156624623b24d3a400f592229-Sauer, Mich>; Callahan, Victoria (OS/ASPR/IO) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95162cb185624a6ebe5fadf08484c141-Callanhan,>; 'Carrie Bueche' <CBueche@cfr.org>
Sent Date:	2020/01/20 12:24:50
From:	Townsend, Frances <FTownsend@MAFGRP.COM>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>; Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>
CC:	Hanson, Elizabeth <ehanson@MAFGRP.COM>
Subject:	This ongoing 2019 novel coronavirus, or COVID-19, outbreak has a number...
Date:	2020/02/17 18:55:31
Priority:	Normal
Type:	Note

All: Below is an outline of questions for tomorrow at CFR. Sorry to get this to you late but it seems the news changes everyday. As you will see I focus mostly on coronavirus as I suspect that's where the interest will be but get to bio weapons toward the end.

I am happy to take additional questions or suggestions. These sessions go quickly and we have time for Q and A so I doubt I will get through it all but wanted you all to have something to look at.

Thanks again for doing this tomorrow.

Best
Fran

This ongoing 2019 novel coronavirus, or COVID-19, outbreak has a number of historic firsts. It's the largest quarantine in world history with China locking down over 60 million people. It's the first mass repatriation of American citizens into a quarantine, climbing over 1,000.

Let's start with some quick basics: what is coronavirus? How contagious? What is the morbidity rate?

How does it compare to SARs and MERs? More/less infectious? Lethal?

Just to put this in perspective every year here in the US we deal with the flu. How many Americans on average die each year from the flu?

But as I mentioned coronavirus has resulted in a number of historic firsts, talk about what you expect could be our scientific firsts and what roadblocks do those scientific firsts confront?

Over the years, global economic interdependence has grown in nearly every industrial sector, including health care. But that means our health care is also globally interdependent on other systems less equipped, less transparent and perhaps less responsible global actors.

China closed the wet market where the coronavirus outbreak began on 1/1, gene sequenced the virus on 1/9 so they could develop a diagnostic test but did not share the gene sequence with the global health community until 1/12.

How transparent and quick was the Chinese response? What should they have done that they failed to do? What were the consequences?

China now claims more than 70K infected and almost 1800 deaths from the virus. But it has been widely reported that the Chinese have underreported both numbers. What are countries' international obligations to report accurately? To whom? How do you know the numbers are accurate?

How does the current outbreak impact the domestic medical supply chain? What steps could or should we consider to enhance supply chain resilience?

What do the numbers suggest to you about what to expect regionally and worldwide? Have numbers peaked? Will they continue to rise? With the cruise ship there are now a total of 15 Americans infected. Do you expect additional cases? What scale? How prepared are we nationally? Locally?

Looking back over the roughly past decade, emerging infectious diseases played a recurring ominous theme. Be it from H1N1, to ebola, then Zika, and now the 2019 novel coronavirus, the threat is clearly not dissipating. When it comes to non-disease natural disasters, the Stafford Act provides a Disaster Relief Fund to enable immediate response. By comparison, there is a small Infectious Diseases Rapid Response Reserve Fund. Do we need a more Stafford Act-like mechanism to enable quicker response and research to these new threats? What other actions can we take to better prepare?

While often we see folks painting emerging infectious diseases and biodefense into separate categories, the truth is that there is significant crossover in terms of preparedness and research. Understanding that this is a sensitive topic, could you talk about how we should approach these risks in a comprehensive manner that can achieve public health and national security objectives concurrently?

I'd like to use this to transition to the topic of bio weapons which is what we originally planned to talk about. The landscape here has also transformed. When BioShield was written and the Strategic National Stockpile established we worried about State actors deploying banned weapons like small pox; plague and hemorrhagic fever. And you still must prepare against those things as well as new and emerging threats like the toxins we have seen deployed by Russia and North Korea in more targeted assassinations.

How do you stay ahead of these threats? Do we have the resources and surveillance that we need to stay ahead of the threat? And ensure the necessary vaccines and therapeutics?

The ebola outbreak may be an instructive example, it seems to be coming under some control despite the precarious security situation in the Democratic Republic of Congo. But the ongoing 2018 outbreak was the second largest in history following the 2013-2016 West African outbreak. As a result of these outbreaks, the United States government has pioneered new FDA-approved diagnostics and vaccines, with promising therapeutics seemingly around the approval corner too. What lessons can we draw from the ebola outbreaks? How do you work with and incentivize industry to develop what you need in the event of a catastrophic bio attack? And How do you make the best possible decisions about the stockpile?

I always worried that because we are global leaders if there was a bio attack or outbreak anywhere in the world, others would look to us and to our stockpile for the answer. Are our global allies doing enough to prepare against these threats--whether they be manmade or natural? Are they maintaining adequate stockpiles of medical countermeasures and research bases--and should they be?

Lastly (if we have time)....the FBI recently arrested a Harvard scientist for accepting undisclosed grant money from China for scientific research. It has now been reported that there are similar investigations at a number of US universities including Yale and MIT to name two and that the grant monies are in the billions. What are foreign governments looking for? Why in the US? Clearly a national security risk, is it a bio weapons concern?

=====

DISCLAIMER: This e-mail message and any attachments are intended solely for the use of the person(s) named in the message header to whom the email is addressed and may contain information that is confidential or legally privileged. If you are not the intended recipient, you are hereby notified that any dissemination, distribution, copying, or other use of this message or its attachments is strictly prohibited. If you have received this message in error, please notify the sender immediately and permanently delete this e-mail message and any attachments (and any copies or printouts of the same).

Sender:	Townsend, Frances <FTownsend@MAFGRP.COM>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>; Conrad, Patricia (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3793ae43a1744d8f8aa56b600c0c975b-patricia.co>; Hanson, Elizabeth <ehanson@MAFGRP.COM>
Sent Date:	2020/02/17 18:55:23
Delivered Date:	2020/02/17 18:55:31

From:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
To:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Subject:	IOS Nightly Note
Date:	2020/01/20 19:24:46
Priority:	Normal
Type:	Note

(b)(5)

(b)(5)

(b)(5)

Other Newsworthy Items:

From Today:

- Dr. Fauci participated in a taped interview for tonight's *CBS Evening News with Norah O'Donnell*. Topic: novel coronavirus.

Sender:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
Recipient:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Sent Date:	2020/01/20 19:24:44
Delivered Date:	2020/01/20 19:24:46

From:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
To:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Subject:	IOS Nightly Note
Date:	2020/01/20 19:24:45
Priority:	Normal
Type:	Note

(b)(5)

(b)(5)

(b)(5)

Other Newsworthy Items:

From Today:

- Dr. Fauci participated in a taped interview for tonight's *CBS Evening News with Norah O'Donnell*. Topic: novel coronavirus.

Sender:	Watters, Sam (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D924DEA65E5C4C098E0CB3FC363A2062-WATTERS, SA>
Recipient:	IOS Nightly Update </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac603d3712a448338b70d3ad0ea131c9-IOS Nightly>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Dareshori, Zack (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e07b941ed04118ab39d2f6e3f2392c-Dareshori,>
Sent Date:	2020/01/20 19:24:44
Delivered Date:	2020/01/20 19:24:45

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #6)
Date:	2020/01/20 20:00:23
Priority:	Normal
Type:	Note

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #6)

The current situation relates to an outbreak of Novel Coronavirus (**2019-nCoV**) in Wuhan City, Hubei Province, China. Some patients were linked to a large local seafood and animal market.

- **218 cases of confirmed 2019-nCoV in 4 countries as of January 20th**
- **CDC is planning for scale up of screening of travelers from Wuhan in multiple airports**
 - **Atlanta (ATL) and Chicago (ORD), in addition to San Francisco (SFO), Los Angeles (LAX) and John F Kennedy (JFK)**
 - **1,120 persons were screened as of 19Jan20 and none were referred for medical evaluation**
- **CDC has activated the Emergency Operations Center in response to the 2019-nCoV outbreak**
- **The CDC laboratory has tested specimens from one patient, which tested negative for the 2019-nCoV using the CLIA-certified real time RT-PCR assay**
 - **Is currently processing specimens from another patient as of 20Jan20**
- **The Global Migration Task Force on 20Jan20, held conference call with city and state health department officials with jurisdiction over the Atlanta (ATL) and Chicago (ORD) airports to discuss traveler entry screening issues**
- **Medical Care and Countermeasures Task Force is working closely with Epi TF on revising Home Care documents with link to guidance on isolation for confirmed patients, as well as patients who test negative but are still under investigation**
- **PPE supply chain partners engaged to increase awareness on supply chain status**
 - **NIOSH is meeting with International Safety Equipment Association (ISEA) and Health Industry Distributors Association (HIDA) on Tuesday for an update on PPE supply chain status.**

For more details, please see attached CDC SITREP for Novel Coronavirus.

The SOC will continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Juan Ospina, Watch Officer

Approved by: Rhibano Dokong, Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
Description: Description: Description: Description: Description:
cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/20 20:00:16
Delivered Date:	2020/01/20 20:00:23

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
To:	(b)(6) OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>
CC:	EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	Secretary's Nightly Update
Date:	2020/01/20 20:01:27
Priority:	Normal
Type:	Note

(b)(5)

(b)(5)

From Today:

- • Dr. Fauci participated in a taped interview for tonight's *CBS Evening News with Norah O'Donnell*. Topic: novel coronavirus.

Sender:	Dareshori, Zack (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4E07B941ED04118AB39D2F6E3F2392C-DARESHORI,>
Recipient:	(b)(6) (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; EDH (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=393ceddbc5fa4d44a9734e20f54c8146-EDH6886>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/01/20 20:01:25
Delivered Date:	2020/01/20 20:01:27

From:	Redd, John (OS/ASPR/SPPR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9BA3FED4EE8646EC849A5A87136A24F6-REDD, JOHN>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
CC:	Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Phillips, Sally (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>; Yeskey, Kevin (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fe6cf13518445fd9c3a1c254e166b3f-Yeskey, Kev>
Subject:	FW: HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #6)
Date:	2020/01/20 20:28:59
Priority:	Normal
Type:	Note

Sir, a couple of things to note beyond the increase in cases to 218:

(b)(5)

John

From: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Sent: Monday, January 20, 2020 8:00 PM
To: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Subject: HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #6)

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #6)

The current situation relates to an outbreak of Novel Coronavirus (**2019-nCoV**) in Wuhan City, Hubei Province, China. Some patients were linked to a large local seafood and animal market.

- **218 cases of confirmed 2019-nCoV in 4 countries as of January 20th**
- **CDC is planning for scale up of screening of travelers from Wuhan in multiple airports**
 - **Atlanta (ATL) and Chicago (ORD), in addition to San Francisco (SFO), Los Angeles (LAX) and John F Kennedy (JFK)**
 - **1,120 persons were screened as of 19Jan20 and none were referred for medical evaluation**
- **CDC has activated the Emergency Operations Center in response to the 2019-nCoV outbreak**

- The CDC laboratory has tested specimens from one patient, which tested negative for the 2019-nCoV using the CLIA-certified real time RT-PCR assay
 - Is currently processing specimens from another patient as of 20Jan20
- The Global Migration Task Force on 20Jan20, held conference call with city and state health department officials with jurisdiction over the Atlanta (ATL) and Chicago (ORD) airports to discuss traveler entry screening issues
- Medical Care and Countermeasures Task Force is working closely with Epi TF on revising Home Care documents with link to guidance on isolation for confirmed patients, as well as patients who test negative but are still under investigation
- PPE supply chain partners engaged to increase awareness on supply chain status
 - NIOSH is meeting with International Safety Equipment Association (ISEA) and Health Industry Distributors Association (HIDA) on Tuesday for an update on PPE supply chain status.

For more details, please see attached CDC SITREP for Novel Coronavirus.

The SOC will continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Juan Ospina, Watch Officer

Approved by: Rhibano Dokong, Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)
 Assistant Secretary for Preparedness and Response (ASPR)
 200 Independence Ave S.W.
 Washington D.C. 20201
 Office: (202) 619 – 7800
 Fax: (202) 619 – 8602
 Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
 Description: Description: Description: Description: Description:
 cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	Redd, John (OS/ASPR/SPPR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9BA3FED4EE8646EC849A5A87136A24F6-REDD, JOHN>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Phillips, Sally (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d6ce8134846423cb83b5b28464edb60-Phillips, S>; Yeskey, Kevin (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fe6cf13518445fd9c3a1c254e166b3f-Yeskey, Kev>
Sent Date:	2020/01/20 20:28:58
Delivered Date:	2020/01/20 20:28:59

From:	Daniel Lucey (b)(6)
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.oup (FYDIBOHF23SPDLT)/cn=Recipients/cn=a104469df5184cc38bf02034af7eca04-Hunt, Richa>
CC:	Herrmann, Jack (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bebe389042ba411496b284f678ce7247-Herrmann, Ja>; Kerr, Lawrence (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre>
Subject:	Thanks
Date:	2020/01/20 22:14:07
Priority:	Normal
Type:	Note

Rick, Much appreciated. I confirmed talk with Syra for Friday. Last January I went to NYC for Syra's SARS simulation in a trailer outside a hospital. They simulated intubation of SARS patients. I felt sick to my stomach because they wear not wearing appropriate PPE for intubation. In Toronto where I worked during SARS, for intubation they learned the hard way to wear a PAPR and put it in writing and a publication. In the debrief Syra asked me twice to comment on the simulation so finally I did. When I pointed out this PPE problem there was an awkward silence including NETEC, the HHS person, and the young NYCDHMH physician. Today could be "Day 1" in America for this Contagious novel Coronavirus. I hope CDC (and NETEC) Preparedness and Response and Day 1 just-in-time training is much better for this Novel coronavirus now, and better than anthrax 2001 for Brentwood workers ("spores don't get out of envelopes" error so no PEP antibiotics until 9 days after exposure) and Ebola 2014 (Dallas PPE and protocol versus hours for PEP in Senate Hart Bldg). We cannot honestly say we did not know what Toronto and Asia learned the hard way when 1,701 health workers got SARS: 1,002 mainland China, 386 Hong King, 209 Canada, 9 Singapore, 68 Taiwan, 36 Vietnam.

On Jan 20, 2020, at 1:04 PM, Hunt, Richard (OS/ASPR/EMMO)
<Richard.Hunt@hhs.gov>wrote:

Dan,

Have communicated w/ Jack on this. We don't see any appearance or real conflict/influence on your current project with us. Glad you've been invited by Syrah to participate in webinar. Please go ahead and do so. Spreading the word on the virus is important.

Thanks,

Rick

From: Daniel Lucey (b)(6)
Sent: Sunday, January 19, 2020 7:14 PM
To: Hunt, Richard (OS/ASPR/EMMO) <Richard.Hunt@hhs.gov>
Cc: Herrmann, Jack (OS/ASPR/OEA) <John.Herrmann@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Daniel Lucey (b)(6)
Subject: nCov in Beijing, Shenzhen, and 136 new cases Wuhan

Rick,

Please see below links to today's terrible news on the novel coronavirus: 1st cases in Beijing and Shenzhen, and 136 new cases in Wuhan on Jan 18: (59 cases) and Jan 19 (77 cases).

NYC H & H Syra Madad invited me to give a webinar this week on this nCov outbreak-become--epidemic.

I am glad to do so (no honorarium offered); however, I want to be 100% sure that doing so does not even appear to influence the go/no go decision pending at ASPR/HHS after deadline is reached for outside comments this Friday, Jan. 24.

If no-go, for any reason, then please advise ASAP so I can pivot quickly and accordingly.

Seeing this SARS-like epidemic rapidly evolving in 2020 in China is a bit eerie and uncanny (given what I wrote as # 2 of the 3 scenarios that are under review until Jan. 24).

Thank you very much,

Dan

Jan 19, 2020 Sunday

Update nCoV EPIDEMIC:

A) 1st Case(s) (N=2) in Beijing Daxing District. See Beijing News url here:

<http://www.bjnews.com.cn/news/2020/01/20/676733.html>

Also, [Sina.com](https://news.sina.com.cn/c/2020-01-20/doc-iihnzakh5231668.shtml) URL for 2 Beijing cases: <https://news.sina.com.cn/c/2020-01-20/doc-iihnzakh5231668.shtml>

Also, China News online URL at: <http://www.chinanews.com/sh/2020/01-20/9064734.shtml>

B). **1st case in Shenzhen:** see Beijing News URL here:

<http://www.bjnews.com.cn/news/2020/01/20/676734.html>

Also, National Health Commission Guangdong (gd.gov.cn) 1st case Shenzhen:

http://wsjkw.gd.gov.cn/zwyw_yqxx/content/post_2876057.html

C) **Wuhan reports 136 new cases** (Jan 18: 59 and Jan 19: 77 cases)

See Beijing News URL Jan 19 at:

<http://www.bjnews.com.cn/news/2020/01/20/676735.html>

Daniel Lucey MD

Sender:	Daniel Lucey <daniel.lucey8@gmail.com>
Recipient:	Herrmann, Jack (OS/ASPR/OEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bebe389042ba411496b284f678ce7247-Herrmann, Ja>; Kerr, Lawrence (HHS/OS/OGA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre>; Hunt, Richard (OS/ASPR/EMMO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a104469df5184cc38bf02034af7eca04-Hunt, Richa>
Sent Date:	2020/01/20 22:13:55
Delivered Date:	2020/01/20 22:14:07

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #7)
Date:	2020/01/20 23:20:13
Priority:	Normal
Type:	Note

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #7)

The WHO Director General is convening the International Health Regulations (IHR) Emergency Committee (EC) for novel coronavirus 2019_nCoV (Wuhan, China) to discuss whether this event constitutes a public health emergency of international concern (PHEIC) and whether the Director-General should issue temporary recommendations on Wednesday, 22Jan20.

- The meeting is only open to Members of the EC and to advisors and other experts informing the Committee.
- WHO will hold a press conference Wednesday, 22Jan20 to announce any recommendations coming from that meeting.

The SOC will and **ASPR IHR program**, continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Juan Ospina, Watch Officer

Approved by: Rhibano Dokong, Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
Description: Description: Description: Description: Description:
cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received

this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/20 23:20:04
Delivered Date:	2020/01/20 23:20:13
Message Flags:	Unread

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #7)
Date:	2020/01/20 23:20:13
Priority:	Normal
Type:	Note

HHS International FYSA: Novel Coronavirus, Wuhan, China (Update #7)

The WHO Director General is convening the International Health Regulations (IHR) Emergency Committee (EC) for novel coronavirus 2019_nCoV (Wuhan, China) to discuss whether this event constitutes a public health emergency of international concern (PHEIC) and whether the Director-General should issue temporary recommendations on Wednesday, 22Jan20.

- The meeting is only open to Members of the EC and to advisors and other experts informing the Committee.
- WHO will hold a press conference Wednesday, 22Jan20 to announce any recommendations coming from that meeting.

The SOC will and **ASPR IHR program**, continue to monitor this incident and report as needed. *This message was sent to the SOC FYSA Distribution List.*

Prepared by: Juan Ospina, Watch Officer

Approved by: Rhibano Dokong, Senior Watch Officer

Secretary's Operation Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



Description: Description: Description: Description: Description:
Description: Description: Description: Description: Description:
cid:image001.png@01CCFC4D.92F36DD0

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received

this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/20 23:20:04
Delivered Date:	2020/01/20 23:20:13

From:	Mike Allen <mike@axios.com>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	Axios AM: Mike's Top 10 — Fast-tracking impeachment — Breaking: Rudy ditches Parnas — Phone frenzy
Date:	2020/01/21 06:04:00
Priority:	Normal
Type:	Note

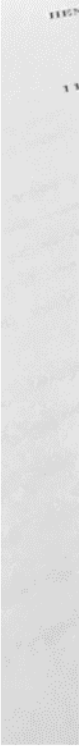


☐☐ **Good Tuesday morning**, and welcome back. Iowa caucuses are 13 days away.

⚡ **Breaking:** "With millions of Asians traveling for the Lunar New Year [Saturday], authorities

• • **"The chilling update** on the coronavirus outbreak ... sent shivers through financial m

1 big thing: Fast-tracking impeachment



McConnell's ground rules. Photo: Jon Elswick/AP

As the Senate impeachment trial of President Trump begins in earnest at 1 p.m., Majority

- • **Look for** very cranky senators. Under the four-page ground rules McConnell's office re
- • **Senators didn't make** dinner plans this week, and expect to be in the chamber until t

With Chief Justice John Roberts presiding, the cellphone ban on the Senate floor, increas

- • **Each day** will begin with the archaic proclamation: "All persons are commanded to ke

Today is all about procedural fights: Democrats will try to force the Senate to allow new witn

- • **Senate Democratic Leader Chuck Schumer** called McConnell's roadmap "deeply

Here's McConnell's plan:

- • **The Senate** will vote today on rules for the trial.
- • **Opening arguments** start tomorrow. House Democratic managers and Trump's defe

- • **Senators will then have** 16 hours to submit their questions to Roberts.
- • **After the Q&A period**, the Senate will vote on whether to consider and debate witnesses.
- • **If the Senate votes yes**, each side can move to subpoena witnesses.
- • **Ultimately**, the Senate will vote on whether to convict the president and remove him from office.

What we learned in the halls: Last week's Government Accountability Office report accusing Trump of abuse of power.

- • **The key argument** Trump's legal team plans to make is that the articles of impeachment are unconstitutional.
- • **But Democrats plan** to highlight the report from the nonpartisan congressional watchdog.

📱 **Catch up quick:** All day, Axios.com will be topped by a constantly updated "smart screen" monitor.

- • **Go deeper:** Read McConnell's 4-page organizing resolution.

f [Share](#)

2. Digital-media breakthrough: Profit



Sender:	Mike Allen <mike@axios.com>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/01/21 06:03:44
Delivered Date:	2020/01/21 06:04:00

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 21Jan20
Date:	2020/01/21 07:06:41
Priority:	Normal
Type:	Note

HHS Executive Summary: Tuesday, 21Jan20

1. HHS

Today's Noteworthy Topics:

Novel Coronavirus, Wuhan, China

The WHO Director General is convening the International Health Regulations (IHR) Emergency Committee (EC) for novel coronavirus 2019_nCoV (Wuhan, China) to discuss whether this event constitutes a public health emergency of international concern (PHEIC) and whether the Director-General should issue temporary recommendations on Wednesday, 22Jan20. The meeting is only open to Members of the EC and to advisors and other experts informing the Committee. WHO will hold a press conference Wednesday to announce any recommendations coming from that meeting. CDC is planning for a scale up of screening of travelers from Wuhan at the Atlanta (ATL) and Chicago (ORD), in addition to San Francisco (SFO), Los Angeles (LAX) and John F Kennedy (JFK) airports. 1,120 people have been screened as of 19Jan20 and none were referred for medical evaluation. CDC has activated the Emergency Operations Center in response to the 2019-nCoV outbreak. The CDC laboratory has tested specimens from one patient, which tested negative for the 2019-nCoV using the CLIA-certified real time RT-PCR assay. The CDC is currently processing specimens from another patient as of 20Jan20. The Global Migration Task Force on 20Jan20, held conference call with city and state health department officials with jurisdiction over the Atlanta (ATL) and Chicago (ORD) airports to discuss traveler entry screening issues. Medical Care and Countermeasures Task Force is working closely with Epi TF on revising Home Care documents with link to guidance on isolation for confirmed patients, as well as patients who test negative but are still under investigation. Personal Protective Equipment (PPE) supply chain partners engaged to increase awareness on supply chain status, and NIOSH is meeting with International Safety Equipment Association (ISEA) and Health Industry Distributors Association (HIDA) today, Tuesday 21Jan20 for an update on PPE supply chain status.

Daily Operational Schedule:

0830 – FEMA Daily Operation Brief

1330 – ASPR Leadership Coordination Call – Bravo Response

Public Health Emergency of National Significance:

Nationwide (Opioid Crisis): 16Oct19

Puerto Rico (Earthquake): 08Jan20

HHS Response Status Summary:

HHS SOC: Level IV (Steady State)

CDC EOC: Level III (Polio/Ebola/Lung Injury/2019_nCoV)

FDA EOC: Level II (Vape product response)

Emergency Support Function (ESF) Activation:

ESF – 8: Not Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 05Mar20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20)

HHS Deployments: (Total = 88)

ASPR: 11 – (3) Irma/Maria, (1) 2018 California Wildfires, (7) 2020 Earthquake Puerto Rico

CDC: 77 – (25) Polio, (50) Ebola, (2) Puerto Rico

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 10 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): 4473-DRPR-HHS-02: FEMA has sent, and HHS has accepted, a mission assignment. As directed by and in coordination with FEMA, Dept. of Health & Human Services (HHS) will provide appropriate personnel to the RRCC, IOF, JFO, or other teams and/or facilities to support FEMA disaster operations. This mission assignment provides \$42,000.00, for a cumulative amount of \$42,000.00, with an estimated projected end date of 06Feb20.

Active Situations (7):

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- ☐ Novel Coronavirus, China
- ☐ Bravo Response
- ☐ Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR

2. FEMA:

Interagency Response Status Summary:

NWC: Monitoring

NRCC: Blue

National IMATs: Red – Fully Mission Capable; Blue – Deployed – PR; Gold – Fully Mission Capable

Regional IMATs: Region I, Reconstituting; Region II, PR; Region VIII, SD

Significant National Weather:

A cold front will move across the Pacific Northwest on Tuesday, bringing low elevation rain and heavy mountain snow. This will be the first of several waves of unsettled weather to impact the region through this week. An upper level disturbance will contribute to development of a storm with rain and snow over the Four Corners. East of this storm, ice is possible from Nebraska to Wisconsin.

3. OPDIV/STAFFDIV Overnight Reports:

CDC: NSTR

FDA: NSTR

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave., S.W.
Washington, D.C. 20201
Office: (202) 619 – 7800
Fax: (202) 619 – 8602
Email: hhs.soc@hhs.gov



cid:image001.png@01D5C478.8EC14C90

CONFIDENTIALITY NOTICE: This e-mail communication and any attachments may contain confidential and privileged information for the use of the designated recipients. If you are not the intended recipient, (or authorized to receive for the recipient) you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please destroy all copies of this communication and any attachments and contact the sender by reply e-mail or telephone (202-619-7800).

Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/01/21 07:06:36
Delivered Date:	2020/01/21 07:06:41