

From: Malone, Kevin M. (CDC/OCOO/OGC)
Sent: Tue, 7 Dec 2021 21:55:47 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Subject: Fwd: Kelley questions

From: Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>
Sent: Monday, November 29, 2021 3:21:31 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>; Tully, Christopher S (HHS/OGC) <Christopher.Tully@HHS.GOV>; Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>
Cc: Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Von Bokern, Jordan L. (CIV) <Jordan.L.Von.Bokern2@usdoj.gov>
Subject: RE: Kelley questions

(b)(5)

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Monday, August 2, 2021 11:03 AM
To: Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>; Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>; Tully, Christopher S (HHS/OGC) <Christopher.Tully@HHS.GOV>; Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>
Cc: Beer, Jocelyn (HHS/OGC) <Jocelyn.Beer@hhs.gov>; Dart, Beverly (OS/OGC/PHD) <Beverly.Dart@hhs.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Von Bokern, Jordan L. (CIV) <Jordan.L.Von.Bokern2@usdoj.gov>
Subject: RE: Kelley questions

I'm available, too.

Kevin

From: Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>
Sent: Monday, August 2, 2021 10:52 AM
To: Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>; Tully, Christopher S (HHS/OGC) <Christopher.Tully@HHS.GOV>; Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>
Cc: Beer, Jocelyn (HHS/OGC) <Jocelyn.Beer@hhs.gov>; Dart, Beverly (OS/OGC/PHD) <Beverly.Dart@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Von Bokern, Jordan L. (CIV) <Jordan.L.Von.Bokern2@usdoj.gov>
Subject: RE: Kelley questions

Works for us, Jocelyn M. and Beverly

From: Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>
Sent: Monday, August 2, 2021 10:28 AM
To: Tully, Christopher S (HHS/OGC) <Christopher.Tully@HHS.GOV>; Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>
Cc: Beer, Jocelyn (HHS/OGC) <Jocelyn.Beer@hhs.gov>; Dart, Beverly (OS/OGC/PHD) <Beverly.Dart@hhs.gov>; Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Von Bokern, Jordan L. (CIV) <Jordan.L.Von.Bokern2@usdoj.gov>
Subject: RE: Kelley questions

Yep

From: Tully, Christopher S (HHS/OGC) <Christopher.Tully@HHS.GOV>
Sent: Monday, August 2, 2021 10:25 AM
To: Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>; Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>
Cc: Beer, Jocelyn (HHS/OGC) <Jocelyn.Beer@hhs.gov>; Dart, Beverly (OS/OGC/PHD) <Beverly.Dart@hhs.gov>; Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Von Bokern, Jordan L. (CIV) <Jordan.L.Von.Bokern2@usdoj.gov>
Subject: Re: Kelley questions

Yes.

On: 02 August 2021 10:15, "Goldberg, Lindsay (HHS/OGC)" <Lindsay.Goldberg@hhs.gov> wrote:

Would 230pm tomorrow work for everyone?

From: Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>
Sent: Friday, July 30, 2021 5:22 PM
To: Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>
Cc: Beer, Jocelyn (HHS/OGC) <Jocelyn.Beer@hhs.gov>; Dart, Beverly (OS/OGC/PHD) <Beverly.Dart@hhs.gov>; Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Tully, Christopher S (HHS/OGC) <Christopher.Tully@HHS.GOV>; Von Bokern, Jordan L. (CIV) <Jordan.L.Von.Bokern2@usdoj.gov>
Subject: Re: Kelley questions

Adding Jordan, but anytime before 3:30pm should work for me most days.

On Jul 30, 2021, at 4:15 PM, Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov> wrote:

Hi Chris – I'd like to set up a meeting next week with all the folks on this email. I'm still trying to nail down everyone's availability, but in the meantime, are there any dates/times that would be best for you? Or dates/times to avoid? Thanks so much.

From: Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>
Sent: Friday, July 16, 2021 9:38 AM
To: Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>
Cc: Beer, Jocelyn (HHS/OGC) <Jocelyn.Beer@hhs.gov>; Dart, Beverly (OS/OGC/PHD) <Beverly.Dart@hhs.gov>; Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>; Mahler, Christian (HHS/OGC) <Christian.Mahler@hhs.gov>; Ackerman, Kathleen (OS/OGC) <Kathleen.Ackerman@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: RE: Kelley questions

Thank you all for your help and your answers so far to my many questions. This is very very helpful. Because the email below is a lot of narrative and there are a lot of you on the chain, I have bolded my primary asks so that they don't get lost, but the explanation of where I am coming from may be useful to all of you going forward, even if these particular questions don't apply to your specific area.

(b)(5)

(b)(5)

I am always happy to discuss any of my questions by phone, if helpful. (b)(5)

(b)(5)

(b)(5)

From: Goldberg, Lindsay (HHS/OGC) <Lindsay.Goldberg@hhs.gov>
Sent: Thursday, July 15, 2021 5:37 PM
To: Lynch, Christopher M. (CIV) <Christopher.M.Lynch@usdoj.gov>
Cc: Beer, Jocelyn (HHS/OGC) <Jocelyn.Beer@hhs.gov>; Dart, Beverly (OS/OGC/PHD) <Beverly.Dart@hhs.gov>; Mendelsohn, Jocelyn S. (HHS/OGC) <Jocelyn.Mendelsohn@hhs.gov>; Mahler, Christian (HHS/OGC) <Christian.Mahler@hhs.gov>; Ackerman, Kathleen (OS/OGC) <Kathleen.Ackerman@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: Kelley questions

Hi Chris – here are two responses I’ve received so far on your Kelley questions. Copying my colleagues in the PHD division in case you have other questions. Bev and Jocelyn M. advise (b)(5) Kevin advises (b)(5) (b)(5) and Kathleen and Chris advise (b)(5) Jocelyn B. and I are of course happy to answer question as well, but I think a group email may be most efficient.

Lindsay S. Goldberg
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Office of the General Counsel - CMS Division
U.S. Department of Health and Human Services
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Washington, DC 20201
Tel: (202) 619-2795
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From: Malone, Kevin M. (CDC/OCOO/OGC)
Sent: Tue, 7 Dec 2021 19:27:22 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Subject: Fw: ABC request for "waiver" for need to verify provider license

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Tuesday, December 7, 2021 2:25 PM
To: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>
Subject: Re: ABC request for "waiver" for need to verify provider license

David -

I have another call at 3 pm today. It makes sense to me that provider medical licenses would be verified before they are sent therapeutics. Copying Susan Sherman and Jenn Ray-Gorrie.

Kevin

From: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Sent: Tuesday, December 7, 2021 1:21 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: FW: ABC request for "waiver" for need to verify provider license

Kevin,

I mentioned you helped with a similar effort before, and I'm afraid you may be pulled into this one as well. Do you have 5min for a quick call?

If so (I don't have your number), please feel free to call either of my numbers below at your convenience.

Thank you,

David Simon

FOUO/Procurement Sensitive

David Simon Ph.D.
Health Scientist
Antiviral Antitoxin Branch
Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)

Office: 202-260-1101
Cell: (b)(5)
Email: David.Simon@hhs.gov

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From: Gillette, Gregory (OS/ASPR/CAG) <Gregory.Gillette@hhs.gov>
Sent: Tuesday, December 7, 2021 1:12 PM
To: Kelleher, Patrick (OS/ASPR/CAG) <Patrick.Kelleher@hhs.gov>; Griffin, Margaret (ASPR/SNS) <ghk9@cdc.gov>; Pfundt, Tiffany (OS/ASPR/IO) <Tiffany.Pfundt@hhs.gov>; Chuk, Meredith (FDA/OC) <Meredith.Chuk@fda.hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>; Kachinski, Kevin (OS/ASPR/CAG) <Kevin.Kachinski@hhs.gov>; Gayda, John (OS/ASPR/CAG) <John.Gayda@hhs.gov>
Cc: Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: ABC request for "waiver" for need to verify provider license

(b)(5)

Regards,

Greg

From: Kelleher, Patrick (OS/ASPR/CAG) <Patrick.Kelleher@hhs.gov>
Sent: Tuesday, December 7, 2021 11:57 AM
To: Gillette, Gregory (OS/ASPR/CAG) <Gregory.Gillette@hhs.gov>
Subject: FW: (b)(5)

SA

Patrick N. Kelleher, SES

Deputy Chief Operating Officer
COVID-19 Countermeasures Acceleration Group (CAG)
(O) 202.969.3811

(b)(5)

patrick.kelleher@hhs.gov

From: Sample, Matthew <MSample@amerisourcebergen.com>
Sent: Tuesday, December 7, 2021 9:14 AM
To: Kelleher, Patrick (OS/ASPR/CAG) <Patrick.Kelleher@hhs.gov>
Cc: Kachinski, Kevin (OS/ASPR/CAG) <Kevin.Kachinski@hhs.gov>; Martin, Jodi (OS/ASPR/CAG) <Jodi.Martin@hhs.gov>
Subject: RE: (b)(6)

It's for all RX products and manufacturers.

(b)(6)

Matt Sample | SVP, Manufacturer Operations | (b)(6) | msample@amerisourcebergen.com

AB

From: Kelleher, Patrick (OS/ASPR/CAG) <Patrick.Kelleher@hhs.gov>
Sent: Tuesday, December 7, 2021 7:55 AM
To: Sample, Matthew <MSample@amerisourcebergen.com>
Cc: Kachinski, Kevin (OS/ASPR/CAG) <Kevin.Kachinski@hhs.gov>; Martin, Jodi (OS/ASPR/CAG) <Jodi.Martin@hhs.gov>
Subject: RE: (b)(6)

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Rgr, is this just for Pfizer or all?

Patrick N. Kelleher, SES
Deputy Chief Operating Officer
COVID-19 Countermeasures Acceleration Group (CAG)
(O) 202.969.3811

(b)(5)

patrick.kelleher@hhs.gov

From: Sample, Matthew <MSample@amerisourcebergen.com>
Sent: Tuesday, December 7, 2021 7:17 AM
To: Kelleher, Patrick (OS/ASPR/CAG) <Patrick.Kelleher@hhs.gov>
Cc: Kachinski, Kevin (OS/ASPR/CAG) <Kevin.Kachinski@hhs.gov>; Martin, Jodi (OS/ASPR/CAG) <Jodi.Martin@hhs.gov>
Subject: Re: (b)(6)

Board of Pharmacy / medical license verification check is what I need waived.

(b)(6)

Matt Sample | c (b)(6)

From: Kelleher, Patrick (OS/ASPR/CAG) <Patrick.Kelleher@hhs.gov>

Sent: Monday, December 6, 2021 10:12:43 PM

To: Sample, Matthew <MSample@amerisourcebergen.com>

Cc: Kachinski, Kevin (OS/ASPR/CAG) <Kevin.Kachinski@hhs.gov>; Martin, Jodi (OS/ASPR/CAG) <Jodi.Martin@hhs.gov>

Subject: RE: (b)(6)

CAUTION: This email originated from outside of the organization. DO NOT CLICK links or open attachments unless you recognize the sender and know the content is safe.

Matt- Copy. BoP= ?

(b)(6)

Pat

Patrick N. Kelleher, SES

Deputy Chief Operating Officer

COVID-19 Countermeasures Acceleration Group (CAG)

(O) 202.969.3811

(M) (b)(6)

patrick.kelleher@hhs.gov

From: Sample, Matthew <MSample@amerisourcebergen.com>

Sent: Monday, December 6, 2021 4:07 PM

To: Kelleher, Patrick (OS/ASPR/CAG) <Patrick.Kelleher@hhs.gov>

Cc: Kachinski, Kevin (OS/ASPR/CAG) <Kevin.Kachinski@hhs.gov>; Martin, Jodi (OS/ASPR/CAG) <Jodi.Martin@hhs.gov>

Subject: FW: (b)(6)

Importance: High

Pat this is the process we have to follow (b)(6)

We are doing EVERYTHING we can to try to lookup BoP in parallel for the ones we don't already have accounts for. I've asked John G. for daily updates of any new sites so my team can constantly work this list.

Let me know if you have any questions on this.

Matt Sample | SVP, Manufacturer Operations | c (b)(6) | msample@amerisourcebergen.com
AB

From: Sample, Matthew
Sent: Wednesday, December 1, 2021 4:38 PM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Pillai, Satish (OS/ASPR/CAG) <Satish.Pillai@hhs.gov>
Cc: Gayda, John (OS/ASPR/CAG) <John.Gayda@hhs.gov>
Subject: (b)(5)

(b)(5)

-Matt

Matt Sample
AmerisourceBergen
SVP, Manufacturer Operations

Phone: 414.374.6504
www.amerisourcebergen.com

United in our responsibility
to create healthier futures.

AB

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From: Malone, Kevin M. (CDC/OCOO/OGC)
Sent: Tue, 7 Dec 2021 15:12:47 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Subject: Fw: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Tuesday, December 7, 2021 10:12 AM
To: Stettner, Joanna L. (CDC/OCOO/OGC) <czl8@cdc.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Vaughn, Brandy (CDC/OCOO/OGC) <wne1@cdc.gov>; Kashdan, Mark S. (CDC/OCOO/OGC) <mtk6@cdc.gov>
Subject: Re: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

From what I recall, 1320b-10 was first approved by Congress primarily because of concerns around Social Security fraud at that time where private entities were trying to have their mailings look like they were from SSA. So, even SSA's brown envelopes were covered under the law as covered publications. Seems that the CDC COVID-19 vaccination cards would also be considered HHS/CDC publications.

Kevin

From: Stettner, Joanna L. (CDC/OCOO/OGC) <czl8@cdc.gov>
Sent: Tuesday, December 7, 2021 10:06 AM
To: Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Vaughn, Brandy (CDC/OCOO/OGC) <wne1@cdc.gov>; Kashdan, Mark S. (CDC/OCOO/OGC) <mtk6@cdc.gov>
Subject: RE: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

I am free as well, I have a call now but should be free from 10:45-12 or between 1-2 or between 3-3:30 or after 4. 1320b-10 is more in Brandy's lane, but I know she's been working with Tamara. I will say that 1320b-10 is really separate from the registration piece as I understand.

From: Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>
Sent: Tuesday, December 7, 2021 9:58 AM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Stettner, Joanna L. (CDC/OCOO/OGC) <czl8@cdc.gov>; Vaughn, Brandy (CDC/OCOO/OGC) <wne1@cdc.gov>; Kashdan, Mark S. (CDC/OCOO/OGC) <mtk6@cdc.gov>
Cc: Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>
Subject: RE: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

Defer to Kash/Brandy/Joanna on the substantive question, but fine to be on a call. My online calendar should be up to date.

Office of the General Counsel

(404) 545-9762

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Tuesday, December 7, 2021 1:04 AM
To: Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Stettner, Joanna L. (CDC/OCOO/OGC) <czi8@cdc.gov>; Vaughn, Brandy (CDC/OCOO/OGC) <wne1@cdc.gov>; Kashdan, Mark S. (CDC/OCOO/OGC) <mtk6@cdc.gov>
Subject: Re: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

+ Mark Kashdan

From: Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>
Sent: Monday, December 6, 2021 9:07 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Stettner, Joanna L. (CDC/OCOO/OGC) <czi8@cdc.gov>; Vaughn, Brandy (CDC/OCOO/OGC) <wne1@cdc.gov>
Subject: FW: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

Hi All,

See below from DOJ - "Could someone at HHS at least speak to the question of whether they view the vaccine cards as "a form, application, or other publication of the Department of Health and Human Services," under 42 U.S.C. § 1320b-10(a)(2)(B)? Various other guidance documents re: fake vaccine cards, like the draft guidance promulgated by the FBI (attached here), have included mentions of that civil provision. But its use really hinges on whether the cards are actually forms or other publications of HHS, and only HHS (not CDC) can really answer that."

I could offer to set up a call with them. Maybe I'm oversimplifying this, but I would think that as an OP/DIV of HHS, CDC could speak to whether the vaccination cards are an HHS publication. Please let me know if you agree with setting up a call and whether you want to join.

Thanks,
Lisa

From: McGarey, Barbara (HHS/OGC) <Barbara.McGarey@hhs.gov>
Sent: Friday, December 3, 2021 3:46 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>
Cc: Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Pierce, Julia (HHS/OGC) <Julia.Pierce@hhs.gov>; Levine, Emily M. (HHS/OGC) <Emily.Levine@hhs.gov>
Subject: FW: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

Kevin and Lisa,

Is it ok if I clarify that you are both the points of contact for these cases and you will coordinate internally to get DOJ the correct information and officials, whether those officials are CDC, other Operating Division or component of HHS, or officials in the Office of the Secretary, HHS? I misinterpreted based on the way he originally asked the question, and I'm feeling like giving him points of contact other than you is just muddying the waters here. Would that be ok with you?

Barb

Barbara M. McGarey
Deputy General Counsel
HHS Office of the General Counsel
She/her/hers
Barbara.McGarey@hhs.gov
(b)(5) (cell)

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From: Bledsoe, Isaac M (OIG/OI) <Isaac.Bledsoe@oig.hhs.gov>
Sent: Friday, December 3, 2021 2:59 PM
To: McGarey, Barbara (HHS/OGC) <Barbara.McGarey@hhs.gov>
Cc: Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: FW: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

Barbara,

Thank you. See below from Samantha Bateman (DoJ). Any thoughts?

- Isaac

Isaac M. Bledsoe
Special Agent
Operations Officer
HHS/OIG/Investigations Branch
(813) 431-7087
isaac.bledsoe@oig.hhs.gov

From: Bateman, Samantha (CRM) <Samantha.Bateman2@usdoj.gov>
Sent: Friday, December 3, 2021 1:42 PM
To: Bledsoe, Isaac M (OIG/OI) <Isaac.Bledsoe@oig.hhs.gov>
Subject: RE: HHS Representative to speak with DoJ (re_Fake Vaccination Card Cases)

Could someone at HHS at least speak to the question of whether they view the vaccine cards as “a form, application, or other publication of the Department of Health and Human Services,” under 42 U.S.C. § 1320b-10(a)(2)(B)?

Various other guidance documents re: fake vaccine cards, like the draft guidance (b)(5) (attached here), have included mentions of that civil provision. But its use really hinges on whether the cards are actually forms or other publications of HHS, and only HHS (not CDC) can really answer that.

Please just let me know – thanks.

Samantha Bateman

Appellate Counsel

U.S. Department of Justice

Criminal Division, Fraud Section

(202) 549-4531

Samantha.Bateman2@usdoj.gov

From: Malone, Kevin M. (CDC/OCOO/OGC)
Sent: Tue, 7 Dec 2021 19:27:00 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Subject: Fw: new studies re infection-induced immunity

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Tuesday, December 7, 2021 1:46 PM
To: Lisiecki, Lucy (HHS/OGC) <Lucy.Lisiecki@hhs.gov>; Myers, Steven A. (CIV) <Steven.A.Myers@usdoj.gov>; Merritt, Robert C. (CIV) <Robert.C.Merritt@usdoj.gov>; DeMott, Joseph (CIV) <Joseph.DeMott@usdoj.gov>; Overing, Kenzie K. (CIV) <Kenzie.K.Overing@usdoj.gov>; Knapp, Cody T. (CIV) <Cody.T.Knapp@usdoj.gov>; Hall, Christopher (CIV) <Christopher.Hall@usdoj.gov>; Wells, Carlotta (CIV) <Carlotta.Wells@usdoj.gov>; Rodriguez, Jimmy (USATXS) <Jimmy.Rodriguez2@usdoj.gov>
Cc: Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Hodges, Katrina (HHS/OGC) <Katrina.Hodges@hhs.gov>; Allred, James (FDA/OC) <James.Allred@fda.hhs.gov>; Alkalay, Barbara (FDA/OC) <Barbara.Alkalay@fda.hhs.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Zeff, Mitchell (HHS/OGC) <Mitchell.Zeff@hhs.gov>
Subject: Re: new studies re infection-induced immunity

Lucy -
Good idea. I'm available on Friday.
Thanks.
Kevin

From: Lisiecki, Lucy (HHS/OGC) <Lucy.Lisiecki@hhs.gov>
Sent: Tuesday, December 7, 2021 1:44 PM
To: Myers, Steven A. (CIV) <Steven.A.Myers@usdoj.gov>; Merritt, Robert C. (CIV) <Robert.C.Merritt@usdoj.gov>; DeMott, Joseph (CIV) <Joseph.DeMott@usdoj.gov>; Overing, Kenzie K. (CIV) <Kenzie.K.Overing@usdoj.gov>; Knapp, Cody T. (CIV) <Cody.T.Knapp@usdoj.gov>; Hall, Christopher (CIV) <Christopher.Hall@usdoj.gov>; Wells, Carlotta (CIV) <Carlotta.Wells@usdoj.gov>; Rodriguez, Jimmy (USATXS) <Jimmy.Rodriguez2@usdoj.gov>
Cc: Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Hodges, Katrina (HHS/OGC) <Katrina.Hodges@hhs.gov>; Allred, James (FDA/OC) <James.Allred@fda.hhs.gov>; Alkalay, Barbara (FDA/OC) <Barbara.Alkalay@fda.hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Zeff, Mitchell (HHS/OGC) <Mitchell.Zeff@hhs.gov>
Subject: RE: new studies re infection-induced immunity

All, I know everyone is extremely busy. Would it be helpful to try to set up a call with Dr. Brooks towards the end of this week, to discuss the developing research on natural immunity? (b)(5)

(b)(5)

(b)(5)

(b)(5) Floating Friday morning as a possible day/time, but please let me know what works for all of you. This is a lengthy distribution list, so perhaps we can shoot to have at least one representative from each group. If this needs to be deferred for a while, that is fine too, but I wanted to make sure it stays on the radar. Thanks, Lucy

From: Myers, Steven A. (CIV) <Steven.A.Myers@usdoj.gov>

Sent: Thursday, December 2, 2021 12:31 PM

To: Lisiecki, Lucy (HHS/OGC) <Lucy.Lisiecki@hhs.gov>; Merritt, Robert C. (CIV) <Robert.C.Merritt@usdoj.gov>; DeMott, Joseph (CIV) <Joseph.DeMott@usdoj.gov>; Overing, Kenzie K. (CIV) <Kenzie.K.Overing@usdoj.gov>; Knapp, Cody T. (CIV) <Cody.T.Knapp@usdoj.gov>; Hall, Christopher (CIV) <Christopher.Hall@usdoj.gov>; Wells, Carlotta (CIV) <Carlotta.Wells@usdoj.gov>; Rodriguez, Jimmy (USATXS) <Jimmy.Rodriguez2@usdoj.gov>

Cc: Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Hodges, Katrina (HHS/OGC) <Katrina.Hodges@hhs.gov>; Allred, James (FDA/OC) <James.Allred@fda.hhs.gov>; Alkalay, Barbara (FDA/OC) <Barbara.Alkalay@fda.hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>

Subject: RE: new studies re infection-induced immunity

Lucy,

Thanks for the heads-up about this. I'm copying Jimmy Rodriguez, since he is counsel of record in *Rodden*, as well as the rest of the Fed Programs EO 14043 team.

Our view at FPB is that while the science may be evolving, (b)(5)

(b)(5) the declaration was accurate when written, there's not a pending motion in the case right now, and Judge Brown did not rely on the declaration in denying the PI motion. That said, Jimmy – it's your name on the docket, so please speak up if you disagree with that take.

(b)(5)

Moving forward, we'd be delighted to have a call next week to make sure we're all on the same page about the current state of the science.

Thanks,
Steve

Steven A. Myers

Senior Trial Counsel

Federal Programs Branch

U.S. Department of Justice, Civil Division

1100 L St. NW, Washington DC 20005

Tel: (202) 305-8648 Fax: (202) 616-8470

From: Lisiecki, Lucy (HHS/OGC) <Lucy.Lisiecki@hhs.gov>

Sent: Thursday, December 02, 2021 12:57 PM

To: Myers, Steven A. (CIV) <Steven.A.Myers@usdoj.gov>; Merritt, Robert C. (CIV) <Robert.C.Merritt@usdoj.gov>; DeMott, Joseph (CIV) <Joseph.DeMott@usdoj.gov>
Cc: Foster, Joseph (CDC/OCOO/OGC) <jb7@cdc.gov>; Hodges, Katrina (HHS/OGC) <Katrina.Hodges@hhs.gov>; Allred, James (FDA/OC) <James.Allred@fda.hhs.gov>; Alkalay, Barbara (FDA/OC) <Barbara.Alkalay@fda.hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>
Subject: [EXTERNAL] new studies re infection-induced immunity

All,

(b)(5)

(b)(5) Would it be helpful to have a call next week about this with Dr. Brooks?

Thanks,
Lucy

Lucy Lisiecki

Currently on detail to the Centers for Disease Control and Prevention

Assistant Regional Counsel

Office of the General Counsel

United States Department of Health and Human Services, Region V

233 North Michigan Avenue, Suite 700

Chicago, Illinois 60601

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From: Malone, Kevin M. (CDC/OCOO/OGC)
Sent: Tue, 7 Dec 2021 19:47:02 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Subject: Fw: Reply by 1PM, 12/09:DHS QFRs:20 Years After 9/11: The State of the Transportation Security Administration

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Tuesday, December 7, 2021 2:45 PM
To: Misrahi, James J. (CDC/OCOO/OGC) <zmr0@cdc.gov>; Friedman, Richard (HHS/OGC) <Richard.Friedman@HHS.GOV>; email.gcl@hhs.gov <email.gcl@hhs.gov>
Cc: Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Howell, Emily C. (CDC/OCOO/OGC) <eph2@cdc.gov>; Epps, Tanya (CDC/OCOO/OGC) <ate0@cdc.gov>; OGC CDC Branch Controls (CDC) <PHDOGCBranchControls@cdc.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>
Subject: Re: Reply by 1PM, 12/09:DHS QFRs:20 Years After 9/11: The State of the Transportation Security Administration

Richard -

Jim Misrahi and I have no comments on these QFRs. Sorry about the delay in responding.
Kevin

From: Misrahi, James J. (CDC/OCOO/OGC) <zmr0@cdc.gov>
Sent: Tuesday, December 7, 2021 11:47 AM
To: Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Howell, Emily C. (CDC/OCOO/OGC) <eph2@cdc.gov>; Epps, Tanya (CDC/OCOO/OGC) <ate0@cdc.gov>; OGC CDC Branch Controls (CDC) <PHDOGCBranchControls@cdc.gov>
Subject: RE: Reply by 1PM, 12/09:DHS QFRs:20 Years After 9/11: The State of the Transportation Security Administration

I have no edits.

Thanks,
Jim

From: Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>
Sent: Tuesday, December 07, 2021 11:20 AM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Misrahi, James J. (CDC/OCOO/OGC) <zmr0@cdc.gov>
Cc: Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Howell, Emily C. (CDC/OCOO/OGC) <eph2@cdc.gov>; Epps, Tanya (CDC/OCOO/OGC) <ate0@cdc.gov>; OGC CDC Branch Controls (CDC) <PHDOGCBranchControls@cdc.gov>
Subject: FW: Reply by 1PM, 12/09:DHS QFRs:20 Years After 9/11: The State of the Transportation

Security Administration

Importance: High

Hi Kevin and Jim,

Can you please review? Just questions #1, 2 and 3. Due 12/9 by 1pm to Leg.

There is some discussion of immigration issues in the later questions (hence why I'm copying Emily), but they don't involve T42.

Thanks.

Kenya

Kenya Ford, J.D.

Deputy for Management and Operations

DHHS Office of the General Counsel

Public Health Division

Centers for Disease Control and Prevention Branch

Telephone: (404) 639-7237

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From: Willoughby, Michelle (HHS/OGC) <Michelle.Willoughby@HHS.GOV>

Sent: Tuesday, December 7, 2021 11:11 AM

To: Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Mccluskie, Sean (HHS/IOS) <Sean.Mccluskie@hhs.gov>; Espinosa, Kimberly (HHS/ASL) <Kimberly.Espinosa@hhs.gov>; Hild, Jeff (HHS/ASL) <Jeff.Hild@hhs.gov>; Kehoe, Brian (HHS/ASL) <Brian.Kehoe@hhs.gov>; Egorin, Melanie (HHS/ASL) <Melanie.Egorin@hhs.gov>; Mullman, Lauren (HHS/ASL) <Lauren.Mullman@hhs.gov>; Palm, Andrea (OS/IOS) <Andrea.Palm@hhs.gov>; Sullivan, Rose (HHS/ASL) <Rose.Sullivan@hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>; Whitley, Edward (HHS/ASL) <Edward.Whitley@HHS.GOV>; Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>; Despres, Sarah (HHS/IOS) <Sarah.Despres@hhs.gov>; Pryor, Rachel (HHS/OS/IOS) <Rachel.Pryor@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>; Dempster, Wesley (OS/ASPR/CAG) <Wesley.Dempster@hhs.gov>; Kessler, David (HHS/IOS) <David.Kessler@hhs.gov>; O'Connell, Dawn (OS/ASPR/IO) <Dawn.Oconnell@hhs.gov>; Pearlman, Aj (HHS/IOS) <Aj.Pearlman@hhs.gov>; Ginieczki, Boyce (AHRQ/IOD) <Boyce.Ginieczki@ahrq.hhs.gov>; Perry, Wendy (AHRQ/OD) <Wendy.Perry@ahrq.hhs.gov>; Clapham, Stephen (OS/ASFR) <Stephen.Clapham@hhs.gov>; Hollinger, Janai (OS/ASFR) <Janai.Hollinger@hhs.gov>; Brisbon, Katrina (HHS/ASFR) <Katrina.Brisbon@hhs.gov>;

Moore, Carlease (HHS/ASFR) <Carlease.Moore@hhs.gov>; Price, Taylor (OS/ASFR) <William.Price1@hhs.gov>; Redding, Tiffani C (HHS/ASFR) <Tiffani.Redding@hhs.gov>; Sealy, Camille (HHS/ASFR) <Camille.Sealy@hhs.gov>; ASPEClearances (OS/ASPE) <ASPEClearances@hhs.gov>; ASPR Legislation (OS/ASPR) <ASPRLEg@hhs.gov>; Wortman, Eric (CDC/OD/CDCWO) <ltr3@cdc.gov>; Durak, Abigail (CDC/OD/CDCWO) <qma0@cdc.gov>; Klingbeil, Martin (CDC/OD/CDCWO) <ypf2@cdc.gov>; Thomas, Marissa (CDC/OD/CDCWO) <KZU2@cdc.gov>; ASAI0 Staff <ASAI0@hhs.gov>; Mordhorst, Lisa (HHS/ASFR) <Lisa.Mordhorst@hhs.gov>; Procopio, Vincenzo (OS/ASA/OBMT) <Vincenzo.Procopio@hhs.gov>; Craig, Nina (IHS/HQ) <Nina.Craig@ihs.gov>; Pete, Darren (IHS/HQ) <Darren.Pete@ihs.gov>; Hodson, Corbrett (IHS/HQ) <Corbrett.Hodson@ihs.gov>; Stevens, Lee (OS/IEA) <Lee.Stevens@hhs.gov>; Robleto, Melissa (HRSA) <MRobleto@hrsa.gov>; Williams, Melissa (HRSA) <MWilliams@hrsa.gov>; Plank-Bazinet, Jennifer (NIH/OD) [E] <jennifer.bazinet@nih.gov>; Higgins, Lauren (NIH/OD) [E] <HigginsL@OD.NIH.GOV>; Vo, Thuy (NIH/OD) [E] <vot@mail.nih.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Brockett, Sharon (HHS/OCR) <Sharon.Brockett@HHS.GOV>; Christensen, David (HHS/OCR) <David.Christensen@hhs.gov>; Durso, Laura (HHS/OCR) <Laura.Durso@hhs.gov>; Frohboese, Robinsue (HHS/OCR) <Robinsue.Frohboese@HHS.GOV>; Henderson, Harold (HHS/OCR) <Harold.Henderson@hhs.gov>; Householder, Donna (HHS/OS) <Donna.Householder@hhs.gov>; Nious, Lionel (HHS/OCR) <Lionel.Nious@HHS.GOV>; OS - OCR OR/ExecSec <OS-OCRORExecSec@hhs.gov>; Thomas, James (HHS/OCR) <James.Thomas@hhs.gov>; Washington, Debra (HHS/OCR) <Debra.Washington@hhs.gov>; Aguirre, Lisa (IOS/ONS) <Lisa.Aguirre@hhs.gov>; Hughes, Barbara (IOS/ONS) <Barbara.Hughes@hhs.gov>; Schmoyer, Michael (OS/ONS) <Michael.Schmoyer@hhs.gov>; OLReview@fda.hhs.gov; Hunter, Ian (CMS/OL) <Ian.Hunter@cms.hhs.gov>; Lewis, Carissa (CMS/OL) <Carissa.Lewis@cms.hhs.gov>; Sanders, Kaylynn (CMS/OL) <Kaylynn.Sanders@cms.hhs.gov>; Talbert, Ada L. (CMS/OL) <Ada.Talbert@cms.hhs.gov>; Kimble, Adrienne (OS/ONC) <Adrienne.Kimble@hhs.gov>; Swain, Matthew (OS/ONC) <Matthew.Swain@hhs.gov>; Maloney, Carol (HHS/ASPA) <Carol.Maloney@hhs.gov>; Formoso, Paula (HHS/ASPA) <Paula.Formoso@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Cc: Friedman, Richard (HHS/OGC) <Richard.Friedman@HHS.GOV>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Blackwell, Edith (HHS/OGC) <Edith.Blackwell@hhs.gov>; Lomax, Tinisha (OS/IOS) <Tinisha.Lomax@hhs.gov>; Main box <IHSlegislation@ihs.gov>; Fisher, Barbara (HHS/OGC) <Barbara.Fisher@HHS.GOV>; Nolan, Janet (HHS/OGC) <Janet.Nolan@hhs.gov>; Teymourtash, Amita (HHS/OGC) <Amita.Teymourtash@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Wiggins, Audrey (HHS/OGC) <Audrey.Wiggins@hhs.gov>; Bess, Demetrice (FDA/OC) <Demetrice.Bess@fda.hhs.gov>; General mail box <ogcfddcontrol@fda.hhs.gov>; Shillingford, Mahala (FDA/OC) <Mahala.Shillingford@fda.hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; OS GCGL, EMAIL (HHS/OS) <OSGCGLEMAIL@hhs.gov>; Naimon, David (HHS/OGC) <David.Naimon@hhs.gov>; OGC PH and S BRANCH CONTROLS <PHandSBRANCHCONTROLS@hhs.gov>; Pierce, Julia (HHS/OGC) <Julia.Pierce@hhs.gov>; Ford, Kenya S. (CDC/OCOO/OGC) <kdf6@cdc.gov>; OGC CDC Branch Controls (CDC) <PHDOGCBranhControls@cdc.gov>; PHD NIH Branch Controlled Correspondence (NIH/OD) <phdnihbrcontrolled@od.nih.gov>; Barclay, Lisa (HHS/OGC) <Lisa.Barclay@hhs.gov>; McGarey, Barbara (HHS/OGC) <Barbara.Mcgarey@hhs.gov>; Rodriguez, Paul (HHS/OGC) <PaulR.Rodriguez@hhs.gov>; OIGClearances@oig.hhs.gov

Subject: Reply by 1PM, 12/09:DHS QFRs:20 Years After 9/11: The State of the Transportation Security Administration

Importance: High

TO: L/H

HRSA

AHRQ	IOS/OS
ASFR	NIH
ASPE	OASH
ASPR	OCR
ATSDR	ONS
CDC	FDA
ASA	CMS
IHS	ONC
IEA	ASPA

FROM: Office of the General Counsel/Legislation Division

SUBJECT: HOMELAND SECURITY Questions for the Record on "20 Years After 9/11: The State of the Transportation Security Administration"

(NOTE: Attached for your review, please find draft DHS (TSA) QFRs from a 9/29 House Homeland Security Committee hearing titled "20 Years After 9/11: The State of the Transportation Security Administration."

Please submit any edits by the deadline below.)

The Office of Management and Budget has asked for the Department's views on this QFRs.

In order that we may respond promptly to this request, please give your comments as soon as possible but no later than 1:00 P.M., THURSDAY, DECEMBER 09 to **both (1) RICHARD FRIEDMAN** of this Division **and (2)** cc: our general e-mailbox (email.gcl@hhs.gov) (Microsoft Outlook users, select: OS GCL, EMAIL from the Global Address List). (Do not share this document(s) outside of the Executive Branch.)

To ensure that the Department's comments are given full consideration, please observe the following guidelines in providing your office's comments:

- Focus on substance -- we generally refrain from making editorial/stylistic comments on other agencies' documents absent errors that would be embarrassing.
- Supply specific recommended changes in the document, in track-changes format where possible; avoid general observations about the document's topic.

- Supply reasons and explanations for all recommended changes, if the reasons are not obvious.

If you have any questions, call the GCL staff attorney named above at 202-690-7766 or our Legislative Reference Service at 202-690-7750.

Attachments

cc: OIG
 GC/IO
 GC/CMS
 GC/CR
 GC/FD
 GC/GLD
 GC/PH
 IOS/OS

Michelle Lawrence Willoughby
Office of the General Counsel/Legislation Division
Legislative Reference Service
202.690.7750 fax 202.690.7309
Michelle.Willoughby@hhs.gov



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From: Malone, Kevin M. (CDC/OCOO/OGC)
Sent: Tue, 7 Dec 2021 19:50:22 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Subject: FW: State licensing follow up - New Pfizer question

From: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Sent: Monday, December 6, 2021 2:51 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: RE: State licensing follow up - New Pfizer question

Kevin,

I hope this email finds you well...and hopefully still working with our CDC colleagues on COVID issues.

(b)(5)

(b)(5)

Otherwise, if you are available for a quick call, I'd like to talk about how we can work through this with this group and our CAG leadership. We can certainly bring in Barry or others from HHS/OGC if you think it's appropriate as well.

I'm available for a call at any time (either number in my signature) to touch base and talk about a way forward with this group.

Thank you,

David Simon

From: Sample, Matthew <MSample@amerisourcebergen.com>
Sent: Friday, December 3, 2021 10:40 AM
To: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Subject: AB License Requirements for AVs/mABs
Importance: High

David,

I was corresponding with my colleagues at Pfizer on an issue we're trying to resolve around the general

distribution (mfg and distributor) to verify Board of Pharmacy licenses for every entity we ship RX product too. This is a huge time process and with the upcoming launch of AVs, we were hoping to mirror the exception McKesson and Pfizer got for Vaccines to not have to do License checks.

Pfizer mentioned you were involved in that effort and Anita too is looking into how we can mirror the vaccine exemption for mAbs & AVs. Do you think it's possible we can connect around getting language for AB that would make my compliance team feel comfortable without doing that check given:

1. States are directing orders to sites
2. States / Sites are required to provide BoP in HPOP
3. Any other policy position that supports this request.

Glad to talk through this live Monday when I'm back in DC.

@Patel, Anita (CDC/DDID/NCIRD/OD) – FYSA

-Matt

Matt Sample

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From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Thursday, August 12, 2021 3:26 PM
To: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Subject: FW: State licensing follow up - DSCSA - Pfizer addition of UPS as a packer/shipper

FYI

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Sent: Thursday, August 12, 2021 1:11 PM
To: Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>; Pillai, Satish (HHS/IOS) <Satish.Pillai@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Santoli, Jeanne (CDC/DDID/NCIRD/ISD) <zmd4@cdc.gov>; Hunt, Christine (FDA/OC) <Christine.Hunt@fda.hhs.gov>; Edmonds, Amanda (FDA/OC) <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: State licensing follow up - DSCSA - Pfizer addition of UPS as a packer/shipper

Dear Satish and Kevin,

We do not think that there are FDA requirements that would be a hindrance to Pfizer enlisting UPS as a third-party logistics (3PL) provider for shipping the vaccine.

Although the Drug Supply Chain Security Act provisions in the FD&C Act impose certain requirements on 3PLs and wholesale distributors, FDA guidance from April 2020 explains that many DSCSA requirements are statutorily lifted for distribution of covered COVID-19 products (including prescription drug products issued under an EUA to combat COVID) to address the public health emergency: <https://www.fda.gov/media/137478/download>.

- To the extent that UPS is engaged in activity that meets the FD&C definition of “wholesale distribution” to address the public health emergency, it would be exempt during the PHE from requirements for wholesale distributors that would otherwise apply.
- One potentially relevant requirement, that according to the guidance may *not* be exempt, is the requirement that DSCSA trading partners, including 3PL’s, be properly “licensed.” But, by statute, all 3PL’s are generally considered “licensed” in advance of FDA issuing and finalizing its rule on wholesale distributor and 3PL licensure, which has not happened yet (582(a)(7) of the FD&C Act (21 USC 360eee-1(a)(7)).

To the extent that the requirements regarding shipping only to licensed providers that UPS are referencing may flow from the CDC provider agreements, we defer to others. If they believe those requirements flow from FDA or state law and it would be helpful for us to weigh in further, let us know. I’ve copied Christine Hunt; the two of us can assist further on this question as needed. I’ve also copied Don and Amanda from FDD for awareness.

Thanks,
Dinesh

Dinesh Kumar
Food & Drug Division, OGC
FDA Office of the Chief Counsel
T: 240.402.0372

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From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, August 11, 2021 8:10 PM
To: Pillai, Satish (OS) <Satish.Pillai@hhs.gov>; Malone, Kevin M (CDC) <kmm2@cdc.gov>
Cc: Patel, Anita (CDC) <bop1@cdc.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; Thombley, Melisa L (CDC) <fsy1@cdc.gov>; Santoli, Jeanne M (CDC) <zmd4@cdc.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Subject: RE: State licensing follow up - Pfizer addition of UPS as a packer/shipper

I have asked Dinesh Kumar of our office , copied here, to respond on this as he has more experience with Drug Supply Chain Security Act issues.

From: Pillai, Satish (OS/ASPR/CAG) <Satish.Pillai@hhs.gov>
Sent: Wednesday, August 11, 2021 6:14 PM
To: Malone, Kevin M (CDC) <kmm2@cdc.gov>
Cc: Beers, Donald <Donald.Beers@fda.hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; Thombley, Melisa L (CDC) <fsy1@cdc.gov>; Santoli, Jeanne M (CDC) <zmd4@cdc.gov>
Subject: Re: State licensing follow up - Pfizer addition of UPS as a packer/shipper

Thanks Kevin - and thanks Jeanne. Don once we have your input, David I think we can quickly reconvene and then engage back with Pfizer

Sent from my iPhone

On Aug 11, 2021, at 6:05 PM, Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov> wrote:

Satish –

As follow-up to our call this afternoon, see the response from Jeanne Santoli below and the attached copy of Anita Patel's Oct. 27, 2020 e-mail to Pfizer. It appears the question is whether UPS can ship to COVID-19 providers enrolled in the CDC COVID-19 Vaccination Program only if their professional licensure status is verified. Anita responded last Fall that the provider agreements for the program require that sites receiving vaccine be able to handle/accept vaccine, provide shipping locations

responsible for vaccine, and provide license numbers for providers at each site, including the Chief Medical Officer's license number. Pfizer/UPS should be able to rely on that.

Copying Don Beers for his input on whether there are any Drug Supply Chain Security Act, or other FDA, requirements that Pfizer could be referencing in their question about bringing UPS onboard as a packer/shipper. Don, you will recall that last Fall we had discussions with Moderna about state pharmacy board requirements for shipment locations. Moderna was informed that those laws had been preempted. I don't think that issue is relevant to Pfizer's current question, since Moderna's concerns had been built on the fact that they were just getting into the business. But, are there possibly other FDA requirements applicable to UPS becoming a packer/shipper for Pfizer?

Also, copying Anita Patel for any additional background she has.

Thanks.

Kevin

From: Santoli, Jeanne (CDC/DDID/NCIRD/ISD) <zmd4@cdc.gov>
Sent: Wednesday, August 11, 2021 3:13 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: RE: State licensing follow up

Kevin: Because they are shipping vaccines directly to providers, Pfizer initially indicated to the USG that they would require significant lead time in order to fulfill orders because of a requirement to validate physician licensure. Anita Patel took the lead in addressing the concern/question raised by Pfizer, based on the requirements of the provider enrollment agreement. I was able to find one email she sent to Pfizer back in October and have attached it to this email. I believe Anita worked with OGC in responding to Pfizer, but I am not sure if it was with your office or with someone in HHS.

I know that Anita has rolled off the VTF, but fortunately she is still actively engaged in the response, currently working under Robert Johnson in HHS, so she is definitely reachable and would probably be able to provide some background on how USG addressed this issue with Pfizer.

Thanks, Jeanne

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Wednesday, August 11, 2021 2:17 PM
To: Santoli, Jeanne (CDC/DDID/NCIRD/ISD) <zmd4@cdc.gov>
Subject: FW: State licensing follow up

Jeanne –

Are you familiar with this issue?

Thanks.

Kevin

From: Pillai, Satish (OS/ASPR/CAG) <Satish.Pillai@hhs.gov>
Sent: Wednesday, August 11, 2021 2:15 PM
To: Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: Fwd: State licensing follow up

Sent from my iPhone

Begin forwarded message:

From: "Pillai, Satish K. (CDC/DDID/NCEZID/DPEI)" <vig8@cdc.gov>
Date: August 10, 2021 at 1:36:19 PM EDT
To: "Pillai, Satish (OS/ASPR/CAG)" <Satish.Pillai@hhs.gov>
Subject: **FW: State licensing follow up**

From: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Sent: Tuesday, August 10, 2021 10:10 AM
To: Duggar, Christopher (CDC/DDID/NCEZID/DVBD) <cnd8@cdc.gov>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>
Cc: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Pillai, Satish K. (CDC/DDID/NCEZID/DPEI) <vig8@cdc.gov>
Subject: FW: State licensing follow up
Importance: High

Chris, Barbara,

I have not seen any answer to Pfizer's question below.

The question regarding UPS is actually quite important, not only for Pfizer, but potentially for USG distribution efforts in the future. Could you please let me know if this is something we can answer and if you have any of the following windows open for a 30min call with Pfizer. They're looking to set something up very soon at UPS which could affect our Domestic distribution. If so, we want to make sure they're doing it according to CDC's needs.

Wednesday: 3-4, 430-500
Thursday: 1030-1130; 2-3, 430-500
Friday: 2-3; 4-5

Thank you,

David Simon

FOUO/Procurement Sensitive

David Simon Ph.D.
Health Scientist
Antiviral Antitoxin Branch
Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)

Office: 202-260-1101

Cell: (b)(5)

Email: David.Simon@hhs.gov

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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES | O'Neill Federal Office Building | Washington, DC 20515

☎ (202) 205-0728 | M (b)(5) | Email: rebecca.lewandowski@hhs.gov

<image003.png>

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From: McKenna, Christine <Christine.McKenna@pfizer.com>

Sent: Tuesday, August 3, 2021 10:10 AM

To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>

Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>; Duggar, Christopher (CDC/DDID/NCEZID/DVBD) <cnd8@cdc.gov>; Timer, Pete <Pete.Timer@pfizer.com>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>

Subject: RE: State licensing follow up

Hi Rebecca,

Of course.

As you know, Pfizer has relied upon USG's representation that all provider sites receiving vaccine had to provide licensing information in order to become COVID-19 vaccine provider locations (see thread below.)

What do you think in terms of next steps?

I have copied Pete who is managing the process of bringing on UPS and can provide any detail I have missed.

Thanks,
Christine

Christine McKenna

Senior Director, US COVID Strategic Partnerships

Cell +1(703) [REDACTED]

From: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>
Sent: Tuesday, August 3, 2021 10:05 AM
To: McKenna, Christine <Christine.McKenna@pfizer.com>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>; Duggar, Christopher (CDC/DDID/NCEZID/DVBD) <cnd8@cdc.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Subject: [EXTERNAL] RE: State licensing follow up

Thank you, Christine.

Would you be able to provide justification for why Pfizer requires the exemption for UPS? That would be a great start in moving needs forward.

Rebecca

Rebecca Lewandowski, PhD | Biologist

Antivirals and Antitoxins Branch

Division of CBRN Countermeasures

Biomedical Advanced Research & Development Authority (BARDA)

Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (DHHS)

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O (202) 205-0728 | M [REDACTED] Email: rebecca.lewandowski@hhs.gov

<image005.png>

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From: McKenna, Christine <Christine.McKenna@pfizer.com>
Sent: Tuesday, August 3, 2021 9:19 AM
To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>; Duggar, Christopher (CDC/DDID/NCEZID/DVBD) <cnd8@cdc.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Subject: RE: State licensing follow up

Hi all,

We have been trying to get a response on this for a few months. Could we arrange a call this week to discuss?

Thank you,
Christine

Christine McKenna
Senior Director, US COVID Strategic Partnerships
Cell (b)(6)

From: McKenna, Christine
Sent: Tuesday, July 27, 2021 5:00 PM
To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>; Duggar, Christopher (CDC/DDID/NCEZID/DVBD) <cnd8@cdc.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Subject: RE: State licensing follow up

Thanks, Rebecca!

Anita/Chris – we have ben trying to find a solution to this question for the last few months. Any chance you can help us get to an answer? Happy to jump on a call.

Thanks,
Christine

Christine McKenna

Senior Director, US COVID Strategic Partnerships

Cell (b)(6)

From: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>
Sent: Tuesday, July 27, 2021 3:20 PM
To: McKenna, Christine <Christine.McKenna@pfizer.com>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>; Duggar, Christopher (CDC/DDID/NCEZID/DVBD) <cnd8@cdc.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Subject: [EXTERNAL] RE: State licensing follow up

Not as of yet, Christine.

I've also Cc'd Anita Patel and Chris Duggar at CDC to try and expedite the turnaround.

Rebecca

Rebecca Lewandowski, PhD | Biologist

Antivirals and Antitoxins Branch

Division of CBRN Countermeasures

Biomedical Advanced Research & Development Authority (BARDA)

Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (DHHS)

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O (202) 205-0728 | **M** (b)(6) | **Email:** rebecca.lewandowski@hhs.gov

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From: McKenna, Christine <Christine.McKenna@pfizer.com>
Sent: Tuesday, July 27, 2021 12:49 PM
To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>
Subject: RE: State licensing follow up

Hi Rebecca,

Any update on this? Anything I can do to help get an answer?

Thanks,
Christine

Christine McKenna

Senior Director, US COVID Strategic Partnerships

Cell (b)(6)

From: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>
Sent: Monday, July 12, 2021 10:01 PM
To: McKenna, Christine <Christine.McKenna@pfizer.com>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Cooper, Barbara (CDC/DDID/NCEZID/DPEI) <bic1@cdc.gov>
Subject: [EXTERNAL] RE: State licensing follow up

Let me check with Barbara at CDC.

Thanks, Christine.

Rebecca

Rebecca Lewandowski, PhD | Biologist

Antivirals and Antitoxins Branch

Division of CBRN Countermeasures

Biomedical Advanced Research & Development Authority (BARDA)

Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (DHHS)

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<image009.png>

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From: McKenna, Christine <Christine.McKenna@pfizer.com>
Sent: Monday, July 12, 2021 9:50 PM
To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>
Subject: RE: State licensing follow up

Thanks, Rebecca!

Every location that receives pharmaceutical products, including pharmacies, must have proper licensing. It is the responsibility of the ship from location (Pfizer, UPS, McKesson, etc.) to ensure the ship to location is properly licensed. Since we are bringing UPS on as a 3PL, Pfizer is requesting that UPS have the same license exemption as Pfizer.

What are some times this week that work for a quick call?

Thanks again,
Christine

Christine McKenna
Senior Director, US COVID Strategic Partnerships
Cell + (b)(6)

From: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>
Sent: Monday, July 12, 2021 5:57 PM
To: McKenna, Christine <Christine.McKenna@pfizer.com>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>
Subject: [EXTERNAL] RE: State licensing follow up

We can make that happen, Christine.

Just for clarity, this is to ensure new pharmacies that product is shipped to are licensed, correct?

Rebecca

Rebecca Lewandowski, PhD | Biologist

Antivirals and Antitoxins Branch

Division of CBRN Countermeasures

Biomedical Advanced Research & Development Authority (BARDA)

Assistant Secretary for Preparedness and Response (ASPR)

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O (202) 205-0728 | **M** (b)(6) | **Email:** rebecca.lewandowski@hhs.gov

<image010.png>

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From: McKenna, Christine <Christine.McKenna@pfizer.com>

Sent: Monday, July 12, 2021 4:32 PM

To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>

Cc: Faircloth, Kyra <Kyra.Rosow@pfizer.com>

Subject: RE: State licensing follow up

Rebecca,

Do you have 30 minutes this week for us to set up time with you to explain this request in more detail so you can help us problem solve? I connected with our team on your suggestion to have UPS engage their representative at the VOC, but the UPS contract for picking and packing orders is with Pfizer and not USG, so the request will not be answered through that UPS team member at the VOC.

Given that Anita was the person who originally worked with us on this licensing point, perhaps we should invite CDC to join as well?

Please let me know what time works best for you. Hopefully if we speak live we can resolve this quickly

Thanks very much,
Christine

Christine McKenna

Senior Director, US COVID Strategic Partnerships

Cell +(b)(6)

From: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>

Sent: Monday, June 28, 2021 1:10 PM

To: McKenna, Christine <Christine.McKenna@pfizer.com>

Cc: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>

Subject: [EXTERNAL] RE: State licensing follow up

Yes!

Thank you, Christine.

Rebecca

Rebecca Lewandowski, PhD | Biologist

Antivirals and Antitoxins Branch

Division of CBRN Countermeasures

Biomedical Advanced Research & Development Authority (BARDA)

Assistant Secretary for Preparedness and Response (ASPR)

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O (202) 205-0728 | M (b)(6) | Email: rebecca.lewandowski@hhs.gov

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From: McKenna, Christine <Christine.McKenna@pfizer.com>

Sent: Monday, June 28, 2021 1:07 PM

To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>

Cc: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>

Subject: RE: State licensing follow up

Yes, I understand. Apologies as I was not on the team in October when this initial response was provided by Anita, but she was the one who originally confirmed that all provider sites receiving vaccine had to provide licensing information in order to become COVID-19 vaccine provider locations. UPS needs this same confirmation provided directly to them as they come online as a 3PL.

I can have UPS reach out to their team member in Vaccine Operation Center if that is the most efficient way forward given that Anita has transitioned off. Is that your advice?

Thank you!
Christine

Christine McKenna
Senior Director, US COVID Strategic Partnerships
Cell (b)(6)

From: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>
Sent: Monday, June 28, 2021 1:02 PM
To: McKenna, Christine <Christine.McKenna@pfizer.com>
Cc: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Subject: [EXTERNAL] RE: State licensing follow up

My understanding is that UPS has a representative in the Vaccine Operation Center in DC, as does CDC.

Rebecca

Rebecca Lewandowski, PhD | Biologist
Antivirals and Antitoxins Branch
Division of CBRN Countermeasures
Biomedical Advanced Research & Development Authority (BARDA)
Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (DHHS)

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the original transmission, attachments and any hard copies.

From: McKenna, Christine <Christine.McKenna@pfizer.com>
Sent: Monday, June 28, 2021 12:51 PM
To: Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>
Cc: Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Subject: FW: State licensing follow up

Rebecca,

Thanks for helping me track this down. See below for the original email thread b/w Pfizer and Anita on this.

(b)(6)

(b)(6)

(b)(6) Can you confirm? Now that Anita has moved on, is there someone else that I should connect the UPS team with on this?

Thank you!
Christine

From: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Sent: Tuesday, October 27, 2020 4:21 PM
To: Faircloth, Kyra <Kyra.Rosow@pfizer.com>; Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Hering, David <David.Hering@pfizer.com>; Cardenas, Melissa <Melissa.Cardenas@pfizer.com>; Paoli, Raymond S <Raymond.Paoli@pfizer.com>; Cetani, Dominick <Dominick.Cetani@pfizer.com>; Dolan, Kathleen A <Kathleen.Dolan@pfizer.com>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Santoli, Jeanne (CDC/DDID/NCIRD/ISD) <zmd4@cdc.gov>; Duggar, Christopher (CDC/DDID/NCEZID/DVBD) <cnd8@cdc.gov>
Subject: [EXTERNAL] RE: State licensing follow up

Hi Kyra,

As part of the provider agreement, sites receiving vaccine must be able to handle/accept vaccine, provide shipping locations responsible for vaccine, provide license numbers for providers at each site. CDC will be providing Pfizer with ship to locations for vaccines. Sites provided will be limited to only those that have the COVID-19 provider agreements submitted to HHS.

Hope this helps.

Best,
Anita

From: Faircloth, Kyra <Kyra.Rosow@pfizer.com>
Sent: Monday, October 26, 2020 10:33 AM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Hering, David <David.Hering@pfizer.com>; Cardenas, Melissa <Melissa.Cardenas@pfizer.com>; Paoli, Raymond S <Raymond.Paoli@pfizer.com>; Cetani, Dominick <Dominick.Cetani@pfizer.com>; Dolan, Kathleen A <Kathleen.Dolan@pfizer.com>
Subject: RE: State licensing follow up

Hi all,

Just following back up on this request.

Hope everyone had a nice weekend!
Kyra

From: Faircloth, Kyra
Sent: Tuesday, October 20, 2020 12:36 PM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Lewandowski, Rebecca (OS/ASPR/BARDA) <Rebecca.Lewandowski@hhs.gov>; Simon, David (OS/ASPR/BARDA) <David.Simon@hhs.gov>
Cc: Hering, David <David.Hering@pfizer.com>; Cardenas, Melissa <Melissa.Cardenas@pfizer.com>; Paoli, Raymond S <Raymond.Paoli@pfizer.com>; Cetani, Dominick <Dominick.Cetani@pfizer.com>; Dolan, Kathleen A <Kathleen.Dolan@pfizer.com>
Subject: State licensing follow up

Rebecca/Anita,

As a follow up to our order discussion just now, here is the email from last week with the slight modification to the original request, highlighted in yellow:

The team has tracked down the exemptions needed to proceed as outlined by Jeanne during our call. As a reminder, Jeannie indicated during the call that the CDC will pass the Ship To locations in their order submission. We shared that we could accommodate that but would need an exemption from the states for validating state licenses and from the FDA for only shipping to authorized trading partners (i.e., licensed facilities) (DSCSA). Will the CDC be validating addresses and performing license checks for these vaccine shipments? Or will you support us in receiving an exemption?

State Licenses

Validating State Pharmacy License from the relevant state licensing authority (e.g., State Board of Pharmacy) (pharmacies, hospitals, clinics, etc.)

OR

Validating State Medical License from the relevant state licensing authority (e.g., State Medical Board) (physicians)

FDA

Verifying authorized trading partner (e.g., dispenser) status (DSCSA)

Kyra

Kyra Faircloth, MS
Senior Director, US Pediatric Pneumococcal Next Generation Commercial lead
Kyra.rosow@pfizer.com

(b)(6)

<image018.png>

-----Original Appointment-----

From: Johnson, Robert (OS/ASPR/CAG) Robert.Johnson@hhs.gov

Sent: Tuesday, August 10, 2021 2:25 PM

To: Johnson, Robert (OS/ASPR/CAG); Johnson, Robert (OS/ASPR/BARDA); Pillai, Satish (HHS/IOS)

Cc: Simon, David (OS/ASPR/BARDA); Gillette, Gregory (HHS/IOS); Malone, Kevin M. (CDC/OCOO/OGC); Duggar, Christopher (CDC/DDID/NCEZID/DVBD); Patel, Anita (CDC/DDID/NCIRD/OD); Barry, Daniel J (HHS/OGC); Russo, Joseph (HHS/IOS)

Subject: Pfizer State Licensing Questions

When: Wednesday, August 11, 2021 2:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: WEBEX/ Dr. Johnson's Office

Good Afternoon,

Tomorrow following the CUB Dr. Johnson would like to discuss Pfizer State Licensing.

(b)(5)

Respectfully,

Major Joseph Russo
O-4, U.S. Marine Corps
Assistant Executive Officer, Chief Operating Officer
Federal COVID-19 Countermeasures Acceleration Group
Office: 202.260.6848
Work Cell: (b)(5)
Personal mobile: (b)(6)
Email: Joseph.Russo@hhs.gov

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<mime-attachment>

From: Malone, Kevin M. (CDC/OCOO/OGC)
Sent: Tue, 7 Dec 2021 18:02:50 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Subject: Fw: Vaccine Lot #'s

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Monday, December 6, 2021 5:09 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Subject: Fw: Vaccine Lot #'s

From: Ahearn, Michael W (OIG/OI) <Michael.Ahearn@oig.hhs.gov>
Sent: Monday, December 6, 2021 4:58 PM
To: Thombly, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Croes, John R (OIG/OI) <John.Croes@oig.hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Driscoll, Ryan P (OIG/OI) <Ryan.Driscoll@oig.hhs.gov>
Subject: RE: Vaccine Lot #'s

Thank you. Would you all potentially have time tomorrow to discuss this issue? I am free most of the day (cc'ing my co-case agent Ryan Driscoll on this email).

Mike Ahearn
Special Agent
HHS-OIG
Hartford Field Office
135 High Street, Suite 268
Hartford, CT 06103
michael.ahearn@oig.hhs.gov

(b)(5) (cell)

From: Thombly, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>
Sent: Monday, December 6, 2021 4:07 PM
To: Croes, John R (OIG/OI) <John.Croes@oig.hhs.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Ahearn, Michael W (OIG/OI) <Michael.Ahearn@oig.hhs.gov>
Subject: RE: Vaccine Lot #'s

Hi John,

Sure, happy to set up a time to discuss. We should be able to work with the Countermeasures Acceleration Group at HHS to pull those lot numbers, with the provider names and date ranges.

Thanks,
Lisa

Lisa Thombley
Senior Attorney
Department of Health & Human Services
Office of the General Counsel
Public Health Division, CDC Branch
E-mail: fsy1@cdc.gov
Telephone: (202) 213-1727

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From: Croes, John R (OIG/OI) <John.Croes@oig.hhs.gov>
Sent: Monday, December 6, 2021 3:24 PM
To: Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Ahearn, Michael W (OIG/OI) <Michael.Ahearn@oig.hhs.gov>
Subject: Vaccine Lot #'s

Lisa / Kevin,

(b)(5)

Please call me direct if you need to discuss, I can give you some high level overview.

But ultimately, I think this is leading to a phone call either way.

Regards,

John
646/285-1595

John Croes
HHS-OIG
Investigations Branch

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Dec 2021 13:20:23 +0000
To: Menschik, David; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Hi David,

Thanks for sharing! I'm noting we're seeing a fair bit of "exposure by breast milk" – does that indicate an increase in reporting of this particular PT?

Also noting "off label use" and other indications of errors among children and teens, something we've observed in reviewing reports among kids 5-11 years.

(b)(5)

Am I seeing an uptick in "vaccine failure"? Wondering if that represents breakthrough infection...

Offhand musings as I wait for the coffee to kick in... Thanks!

--John

From: Menschik, David <David.Menschik@fda.hhs.gov>
Sent: Tuesday, December 7, 2021 6:23 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Nair, Narayan (FDA/CBER) <Narayan.Nair@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>
Subject: RE: Weekly data mining

Good morning,

(b)(6)

(b)(6)

(b)(6)

Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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