one or more sources of two-factor authentication credentials that will be interoperable with their applications. Additionally, an IFR provision, 21 CFR 1311.105, requires that a CSP providing EPCS authentication credentials be approved by the General Services Administration Office of Technology Strategy/Division of Identify Management to conduct identity proofing at Assurance Level 3 or above of NIST SP 800–63–1 (*i.e.,* Identity Assurance Level 2 or above of NIST SP 800–63–3). DEA has received questions asking for clarification of this requirement. *DEA is seeking comment on this approach to identity proofing, as well as any more comments about whether clarification of the language regarding CSP approval would be helpful.*

3. DEA emphasizes that institutional practitioners are allowed, but not required, to conduct identity proofing. If an institutional practitioner decides to have each practitioner obtain identity proofing and the two-factor authentication credential on his or her own, as other individual practitioners do, that is permissible under the rule. *DEA is seeking comment on this approach to identity proofing by institutional practitioners.*

• DEA is also seeking comment on the methods institutional practitioners are using to validate the identity of practitioners remotely. For example, are institutions viewing practitioners' driver's licenses or other forms of identification remotely using video?

4. The IFR requires that any setting of or change to logical access controls related to the issuance of controlled substance prescriptions be defined as an auditable event and that a record of the changes be retained as part of the internal audit trail. *DEA is seeking comment on this approach to logical access control for individual practitioners. In particular, DEA is seeking comment on whether there are any adjustments that DEA could make to this requirement that would reduce its burden on practitioners while still protecting the integrity of EPCS.*

5. As explained above, the IFR sets requirements for how institutional practitioners must establish logical access control for their electronic prescription applications. Among other things, the IFR requires that at least two individuals from the institution's credentialing office provide the part of the institution that controls the computer applications with the names of practitioners authorized to issue controlled substance prescriptions. The entry of the data that grant access to practitioners also requires the involvement of at least two individuals, one to enter the data and another to approve the entry. The institutional registrant is responsible for designating and documenting individuals or roles that can perform these functions. And a practitioner's access must be revoked whenever any of the following occurs: The institutional practitioner's or, where applicable, individual practitioner's DEA registration expires without renewal, or is terminated, revoked, or suspended; the practitioner reports that a token or other factor associated with the two-factor authentication credential has been lost or compromised; or the individual practitioner is no longer authorized to use the institutional practitioner's application. *DEA is seeking comment on this approach to logical access control for institutional practitioners.*

6. The IFR requires that security events—auditable events that compromise or could compromise the integrity of the prescription records of an electronic prescription application—be reported to both the application's provider and DEA within one business day. *DEA is seeking comment from EPCS application users on whether they have experienced a security incident and, if so, whether they have experienced any difficulties reporting it.*

7. *DEA is generally seeking comment on any aspects of the IFR or other EPCS areas where further clarification would be helpful. For example:*

• What types of issues have registrants encountered during the adoption and implementation of EPCS into their workflow, particularly where a prescriber uses an electronic health record (electronic medical record)?

• What types of devices are currently being used to create, sign, transmit, and process controlled substances electronically? For example, are practitioners using iOS or Android mobile devices, Chromebooks, Windows Laptop/Desktops, Mac OS, or others?

• Are there problems using two-factor authentication due to the method used to complete verification (*e.g.,* prohibited or limited cellular service, restriction on external USB devices, offline system access)?

• Has two-factor authentication caused barriers to efficient workflows?

• Have staff workflows at long-term and post-acute care facilities faced barriers during the adoption and implementation of EPCS?

8. Many institutions have implemented biometrics as part of their authentication credentialing for electronic applications. *DEA is seeking comments in response to the following questions:*

• What types of biometric authentication credentials are currently being utilized (*e.g.,* fingerprint, iris scan, handprint)?

• How has the implementation of biometrics, as an option for meeting the two-factor authentication requirement, benefited the EPCS program?

• Are there alternatives to biometrics that could result in a greater adoption rate for EPCS while continuing to meet the authentication requirements? If so, please describe the alternative(s) and indicate how, specifically, it would be an improvement on the authentication requirements in the IFR.

9. Previous commenters have expressed concern regarding failed transmissions of electronic prescriptions. *DEA is seeking comment in response to the following questions:*

• Have any entities experienced failed transmissions (*e.g.,* an EPCS being sent to the wrong pharmacy, an incorrectly filled out EPCS, an EPCS fails to send, the pharmacy does not have the prescribed controlled substance in stock, or the pharmacy rejects the EPCS)?

• If any failed transmissions have occurred, what alternative means of submitting the prescription to the pharmacy have been used?

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–07085 Filed 4–20–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 328

[Docket ID FEMA–2020–0018]

Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use; Exemptions

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notification of exemptions.

SUMMARY: The Federal Emergency Management Agency (FEMA) announces exemptions from a temporary final rule that FEMA published in the **Federal Register** on April 10, 2020.

DATES: *Applicability date:* This notification applies beginning on April 17, 2020.

ADDRESSES: You may review the docket by searching for Docket ID FEMA–2020–

0018, via the Federal eRulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel McMasters, Program Analyst, Office of Policy and Program Analysis, 202–709–0661, *FEMA-DPA@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

On April 10, 2020, the Administrator of the Federal Emergency Management Agency Administrator (FEMA Administrator or the Administrator) published a temporary final rule (the ''rule'') to allocate certain scarce or threatened materials for domestic use, so that these materials may not be exported from the United States without explicit approval by FEMA.[1] The rule aids the response of the United States to the spread of COVID–19 by ensuring that certain scarce or threatened health and medical resources are appropriately allocated for domestic use.[2]

The Administrator issued the rule under the authority of the Defense Production Act of 1950, as amended (DPA),[3] and related executive orders and delegations.[4] Most prominently, on April 3, 2020, the President signed a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (Memorandum).[5] In the Memorandum, the President directed the Secretary of Homeland Security, through the Administrator, and in consultation with the Secretary of Health and Human Services (HHS), to use any and all authority available under section 101 of the DPA to allocate to domestic use, as appropriate, five types of personal protective equipment (PPE) materials (covered materials).

Consistent with the Memorandum, the rule provides that until August 10, 2020, and subject to certain exemptions, no shipments of covered materials may leave the United States without explicit approval by FEMA.[6] The rule requires U.S. Customs and Border Protection (CBP), in coordination with such other officials as may be appropriate, to notify FEMA of an intended export of covered materials.[7] CBP must temporarily detain any shipment of such covered materials pending the Administrator's determination whether to return for domestic use, issue a rated order for, or allow the export of part or all of the shipment.[8] In making such determination, the Administrator may consult other agencies and will consider the totality of the circumstances, including: (1) The need to ensure that scarce or threatened items are appropriately allocated for domestic use; (2) minimization of disruption to the supply chain, both domestically and abroad; (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns; (4) the quantity and quality of the materials; (5) humanitarian considerations; and (6) international relations and diplomatic considerations.[9]

In addition to providing for the determination described above, the rule includes one exemption to the requirement that covered materials not leave the United States without explicit approval by FEMA. In the interest of promoting the national defense, the Administrator determined to generally allow the export of covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of such covered materials, on a per item basis, was distributed in the United States in the preceding 12 months.[10] If FEMA determines that a shipment of covered materials falls within this exemption, such materials may be exported without further review by FEMA, provided that the Administrator may waive this exemption and fully review shipments of covered materials, if the Administrator determines that doing so is necessary or appropriate to promote the national defense.[11]

Pertinent to this notification, the rule also provides that the Administrator may establish, in his discretion, additional exemptions that he determines necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the **Federal Register**. This notification announces such exemptions.

Notice of Additional Exemptions

Pursuant to 44 CFR 328.102(d)(2), section 101 of the DPA, and related authorities, the Administrator has determined that it is necessary and appropriate in order to promote the national defense to exempt certain categories of covered materials from the requirements of 44 CFR 328.102(a) and (b). The Administrator may waive any of these exemptions at any time and fully review shipments of covered materials under 44 CFR 328.102(b) if the Administrator determines that doing so is necessary or appropriate to promote the national defense. In addition, if CBP believes that any manufacturer, broker, distributor, exporter, or shipper of any covered materials is intentionally modifying its shipments in a way to take advantage of one or more of these exemptions, diverting materials from the United States market, or otherwise trying to circumvent the FEMA review requirements in 44 CFR 328.102(b) through application of any of the exemptions, CBP may detain a shipment and forward information about that shipment (including the basis for CBP's belief) to FEMA for determination.

For exemptions (2), (3), (4), (8), and (9), below, FEMA will require a letter of attestation to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials. The letter should be submitted to CBP with other documentation related to the shipment, and contain the following information:

(1) A description of which exemption(s) the exporter is claiming.

(2) Details regarding the shipment that are sufficient for the CBP and FEMA officials to determine whether the shipment falls under the claimed exemption(s).

(3) A statement that the provided information is true and accurate to the best of the exporter's knowledge, and that the exporter is aware that false information is subject to prosecution under the DPA, as outlined in the allocation order.

Exporters who have concerns about how to file this letter of attestation should reach out to CBP to request additional details.

The exemptions are as follows.

(1) *Shipments to U.S. Commonwealths and Territories, Including Guam, American Samoa, Puerto Rico, U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (Including Minor Outlying Islands).* The Administrator issues this exemption to clarify that shipments to U.S. territories are not

[1] *See* 85 FR 20195 (Apr. 10, 2020) (codified at 44 CFR part 328).

[2] *See* 44 CFR 328.101.

[3] 50 U.S.C. 4501 *et seq.*

[4] *See* 85 FR at 20196–20197.

[5] *See* Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use for the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Administrator of the Federal Emergency Management Agency (Apr. 3, 2020), *https://www.whitehouse.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/.*

[6] 44 CFR 328.102(a).

[7] 44 CFR 328.102(b).

[8] *Id.*

[9] 44 CFR 328.102(c).

[10] 44 CFR 328.102(d)(1).

[11] *Id.*

considered to be ''exports'' for purposes of the implementation of the allocation order. The Administrator believes that this exemption is necessary to clarify the scope of the original allocation order and to ensure that scarce or threatened items are allocated for the use of all Americans, including Americans living in U.S. territories. The Administrator believes that ensuring widespread access by Americans to covered materials is necessary and appropriate to promote the national defense and consistent with the purposes of the Presidential Memorandum and the subsequent allocation order to provide for the needs of all Americans.

(2) *Exports of Covered Materials by Non-profit or Non-governmental Organizations that are Solely for Donation to Foreign Charities or Governments for Free Distribution (Not Sale) at their Destination(s).* The Administrator believes that it is necessary and appropriate to promote the national defense to support the efforts of domestic and international non-profit and non-governmental organizations (NGOs) responding to COVID–19 around the world, in response to the humanitarian concerns that have arisen as a result of this global pandemic, and consistent with the position of the United States as a world leader. A key element of national defense is the ability of the United States to convey international leadership during times of crisis, including the COVID–19 pandemic. This includes our ability to exercise moral leadership, help those in need, and to remain stalwarts of the international community. Denying shipments of humanitarian goods would undermine U.S. diplomacy and messaging internationally, allowing strategic competitors to take advantage of our absence. The allocation order recognizes the importance of humanitarian considerations by specifying it as an explicit factor to be considered in making determinations about whether to allow an export to proceed or to utilize the purchase domestically. This exemption creates a limited definition of what constitutes a humanitarian shipment for purpose of the exemption by limiting the exemption both on the exporter side (by limiting it to non-profit organizations or NGOs) and on the recipient side (foreign governments or charities). Further, the exemption is limited by specifying that the goods must be shipped as donations in kind and cannot be sold upon receipt. This limited exemption will allow FEMA to meet the goals of the allocation order while prioritizing review of commercial shipments most likely to be needed for domestic use.

FEMA will require a letter of attestation to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials.

(3) *Intracompany Transfers of Covered Materials by U.S. Companies from Domestic Facilities to Company-owned or Affiliated Foreign Facilities.* The Administrator recognizes the international nature of many U.S. companies, and believes that allowing these companies to continue to produce at a high level is crucial to the functioning of the U.S. economy. One of the factors specifically identified in the allocation order as being critical for the national defense is minimization of disruption of the supply chain, both domestically and abroad. The Administrator believes that allowing this exemption would minimize disruption to the domestic supply chain, while not causing a detrimental shortage of covered materials to Americans.

FEMA will require a letter of attestation to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials.

(4) *Shipments of Covered Materials that are Exported Solely for Assembly in Medical Kits and Diagnostic Testing Kits Destined for U.S. Sale and Delivery.* The Administrator recognizes that, in many circumstances, materials destined for domestic use are assembled in other countries, prior to being returned to the United States for domestic distribution. One of the factors specifically identified in the allocation order as being critical for the national defense is the minimization of disruption of the supply chain, both domestic and abroad. The Administrator believes that allowing the shipments of these kits is important to allow for uninterrupted continuation of existing supply chains, and is the most expedient means to ensure timely delivery and allocation of these materials within the United States to respond to the national emergency. Relying on existing supply chains where available and efficient will maximize the ability for FEMA and CBP to focus limited resources on areas where the supplies are being shipped outside the United States for final disposition. As noted above, the Administrator believes that ensuring widespread access by Americans to covered materials is necessary and appropriate to promote the national defense and consistent with the purposes of the Presidential Memorandum, and the subsequent allocation order, to provide for the needs of Americans.

FEMA will require a letter of attestation to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials.

(5) *Sealed, Sterile Medical Kits and Diagnostic Testing Kits Where Only a Portion of the Kit is Made Up of One or More Covered Materials That Cannot be Easily Removed Without Damaging the Kits.* The Administrator believes that detaining shipments containing these kits, and subsequently attempting to separate the covered materials from the kits (potentially destroying the kits in the process), is an inefficient use of national defense resources. In addition, ready-to-use sealed, sterile medical kits are vital for the healthcare community globally to continue to meet broader urgent healthcare needs in the context of the pandemic. Addressing the related healthcare needs globally will enable other countries to best respond to and contain the pandemic, which will advance the ability of the United States Government to best contain the pandemic within the United States. The Administrator believes that refraining from needlessly dismantling valuable kits is necessary and appropriate to promote the national defense and consistent with the purposes of the Presidential Memorandum, and the subsequent allocation order, to provide for the needs of Americans.

(6) *Declared Diplomatic Shipments from Foreign Embassies and Consulates to their Home Countries. These May be Shipped via Intermediaries (Logistics Providers) but are Shipped from and Consigned to Foreign Governments.* Pursuant to the diplomatic interests of the United States, the Administrator believes that it is necessary and appropriate to promote the national defense to allow diplomatic shipments to proceed without interruption or delay. One of the factors specifically identified in the allocation order as being critical for the national defense is international relations and diplomatic concerns. The Administrator believes that stopping these types of shipments would cause significant international relations and domestic concerns, while not providing significantly enhanced access to covered materials for Americans. In order to continue to foster positive diplomatic relationships with our partners and allies, the Administrator has determined to exempt diplomatic shipments from the allocation order.

(7) *Shipments to Overseas U.S. Military Addresses, Foreign Service Posts (e.g., Diplomatic Post Offices), and Embassies.* The Administrator believes the intent of the Presidential Memorandum is to protect Americans by ensuring their access to covered materials. The Administrator believes this extends to all Americans, including those serving our country overseas. For this reason, the Administrator believes that it is necessary and appropriate to promote the national defense to allow shipments of covered materials to be shipped overseas to U.S. government employees working abroad.

(8) *In-Transit Merchandise: Shipments in Transit through the United States with a Foreign Shipper and Consignee, Including Shipments Temporarily Entered into a Warehouse or Temporarily Admitted to a Foreign Trade Zone.* The April 3 Presidential Memorandum states that ''To ensure that these scarce or threatened PPE materials *remain in the United States* for use in responding to the spread of COVID–19, it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries from diverting such material overseas'' (emphasis added).[12] The Administrator believes that merchandise merely passing through the United States is outside the scope of the Presidential Memorandum. In addition, the Administrator believes that diversion of these specific types of materials would cause significant impacts to international relations, diplomacy, and global supply chains, each of which is a factor that is specifically identified in the allocation order as being necessary and appropriate to promote the national defense. Therefore, the Administrator is explicitly exempting these shipments from the enforcement of the allocation order.

FEMA will require a letter of attestation to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials.

(9) *Shipments for Which the Final Destination is Canada or Mexico.* The Administrator recognizes the important role our closest neighbors play in the national defense interests of the United States. The integration of the economies and supply chains among the United States, Mexico, and Canada is robust. Many critical sectors—including, for example, food and agriculture; communications and energy; automotive and industrial; water and wastewater management; and law enforcement and first responders—cross national boundaries. Negative impacts to workers, including a lack of PPE, in these and other critical sectors in Canada and Mexico may cause significant interruptions to the corresponding supply chains in the United States, and in turn, may disrupt the large flow of cross-border trade with our neighbors. In addition, the United States maintains close economic and diplomatic ties with these nations, which would be negatively impacted by the restriction of exports of covered materials into these countries. In the allocation order, the Administrator specifically identified minimization of disruption to the supply chain, both domestically and abroad, and international relations and diplomatic considerations as key elements of promoting the national defense. Each would be negatively impacted by slowing or halting the transportation of covered materials across country lines to Canada and Mexico. For these reasons, the Administrator has determined that this exemption is necessary and appropriate to promote the national defense.

FEMA will require a letter of attestation stating that the items being shipped are for use in and not for transshipment through Canada or Mexico, to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials.

(10) *Shipments by or on behalf of the U.S. Federal Government, including its Military.* The Administrator recognizes that any shipment of covered materials made by or on behalf of the Federal Government, including its military, are inherently necessary and appropriate to promote the national defense, and so should be exported without delay.

Peter T. Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–08542 Filed 4–17–20; 4:15 pm]

BILLING CODE 9111–19–P

[12] *See* Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use for the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Administrator of the Federal Emergency Management Agency, sec. 1 (Apr. 3, 2020), *https://www.whitehouse.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 160 and 164

Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID–19 Nationwide Public Health Emergency

AGENCY: Office of the Secretary, HHS.

ACTION: Notification of enforcement discretion.

SUMMARY: This notification is to inform the public that the Department of Health and Human Services (HHS) is exercising its discretion in how it applies the Privacy, Security, and Breach Notification Rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). As a matter of enforcement discretion, the HHS Office for Civil Rights (OCR) will not impose penalties for noncompliance with the regulatory requirements under the HIPAA rules against covered health care providers in connection with the good faith provision of telehealth during the COVID–19 nationwide public health emergency.

DATES: The Notification of Enforcement Discretion went into effect on March 17, 2020, and will remain in effect until the Secretary of HHS declares that the public health emergency no longer exists, or upon the expiration date of the declared public health emergency, including any extensions, (as determined by 42 U.S.C. 247d),[1] whichever occurs first.

FOR FURTHER INFORMATION CONTACT: Rachel Seeger at (202) 619–0403 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

I. Background

The Office for Civil Rights (OCR) at the Department of Health and Human Services (HHS) is responsible for enforcing certain regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[2] as amended by the Health

[1] Public Health Emergency Declaration issued by HHS Secretary, pursuant to Section 319 of the Public Health Service Act, on January 31, 2020, with retroactive effective date of January 27, 2020. For more information, see *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] Due to the public health emergency posed by COVID–19, the HHS Office for Civil Rights (OCR) is exercising its enforcement discretion under the conditions outlined herein. We believe that this guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA). 5 U.S.C. 553(b)(3)(A). OCR additionally finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice