DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[CDC Docket No. CDC–2020–0013]

RIN 0920–AA75

Control of Communicable Diseases; Foreign Quarantine

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Interim final rule with request for comments.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS) is issuing this interim final rule to amend its Foreign Quarantine regulations, to enable CDC to require airlines to collect, and provide to CDC, certain data regarding passengers and crew arriving from foreign countries for the purposes of health education, treatment, prophylaxis, or other appropriate public health interventions, including travel restrictions.

DATES:

Effective date: This interim final rule is effective on February 7, 2020.

Comment date: Written comments are invited and must be submitted on or before March 13, 2020.

Expiration date: Unless extended after consideration of submitted comments, this interim final rule will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule. The Secretary will publish a document in the **Federal Register** announcing the expiration date.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be made available to the public. Comments must be identified by RIN 0920–AA75. Because of staff and resource limitations, comments must be submitted electronically to *www.regulations.gov.* Follow the ''Submit a comment'' instructions.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received, as they are public records. Comments may be submitted anonymously.

Comments: You may submit electronic comments on this interim final rule to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. Before or after the close of the comment period, CDC will post all comments that were received before the end of the comment period on *www.regulations.gov.* Follow the search instructions on that website to view the public comments.

FOR FURTHER INFORMATION CONTACT: Christopher De La Motte Hurst, Health Scientist, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329; Telephone: 404–498–1600; Email: *dgmqpolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Current Outbreak of 2019–nCoV

On December 31, 2019, the People's Republic of China (China) notified the World Health Organization (WHO) of pneumonia cases of an unknown cause in Wuhan, China. The United States now has confirmed cases of individuals who have this severe acute respiratory illness caused by a novel (new) coronavirus (''2019–nCoV'') (''the virus'') first detected in Wuhan, Hubei Province, China. On January 30, 2019, the World Health Organization (WHO) declared the outbreak of the 2019–nCoV virus in China a Public Health Emergency of International Concern.[1] WHO indicated that it is expected that further international exportation of cases may appear in any country, and that countries should place particular emphasis on reducing human infection, prevention of secondary transmission, and international spread of the disease. As of February 1, 2020, Chinese health officials have reported approximately 11,953 confirmed cases of infections with 2019–nCoV in China, with an additional 15,238 suspected cases.[2] China now has more confirmed cases of 2019–nCOV than it had of severe acute respiratory syndrome (''SARS'') in 2002–2003. As of February 1, 2020, the virus has killed at least 259 people, all in China.

Outside of China, there are approximately 164 confirmed cases as of February 1, 2020. In one day, the total number of confirmed cases around the world rose from 9,707 to 11,953—an increase of nearly 20 percent. The virus was discovered in China in December 2019. There are now reports of infected people in 28 countries, including those who have not visited China. Those individuals are in Germany, Japan, Taiwan, and Vietnam, among other countries. As of February 1, 2020, there were 8 confirmed cases in the United States.

The 2019–nCoV

Coronaviruses are a large family of viruses. Some cause illness in people and others circulate among animals, including camels, cats, and bats. Animal coronaviruses are capable of evolving and infecting people and then spreading between people, as occurred with Middle East respiratory syndrome (MERS) and SARS.

Coronaviruses can cause illnesses ranging in severity from mild upper respiratory symptoms, similar to the common cold, to severe illnesses, such as those caused by SARS and MERS. Signs and symptoms of 2019–nCoV include fever, cough, and difficulty breathing. The virus has the potential to cause severe illness and death—with persons that have underlying health conditions possibly at higher risk. However, many with the virus experience mild symptoms. U.S. and international health officials are continuing to study the virus to determine its characteristics, including its transmissibility and fatality rate, and to develop diagnostic tests, vaccines, and therapeutics.

Outbreaks of novel virus infections among people are always of public health concern. Older adults and people with underlying health conditions may be at increased risk.

As noted, public health experts are still in the process of studying the virus, including the severity of the virus. The cases that have been identified skew to the severe, including patients who are older or have other illnesses. Experts are working to understand the incubation period. The incubation period for coronaviruses varies; known coronaviruses have incubation periods ranging anywhere from 2 to 14 days. But that period could be higher or lower for this virus. China and Germany have

[1] Under the International Health Regulations, a public health emergency of international concern is ''an extraordinary event'' that constitutes a ''public health risk to other States through international spread of disease and to potentially require a coordinated international response.''

[2] Suspected cases as of January 31, 2020.

reported that there may be evidence of asymptomatic transmission.

Travel Restrictions

In light of the rapid spread of the virus, Chinese authorities have imposed strict travel restrictions in the area around Wuhan. China has taken unprecedented steps to help control the virus. Currently, there are at least 16 cities in China that are under travel restrictions and 26 of China's provincial-level jurisdictions are on high health alert. Beijing city government has suspended all inter-province bus service.

But these precautions have not stopped the virus from spreading to areas of China outside of Hubei Province, as well as to other countries. As many as 5 million individuals are reported to have left Wuhan prior to the imposition of intra-China travel restrictions. Neighboring countries have taken swift action to protect their citizens by restricting travel between their countries and China.

On January 29, President Trump designated the Secretary of Health and Human Services to lead an interagency task force on the novel coronavirus. On January 30, 2020, the U.S. Department of State issued a ''Level 4: Do Not Travel'' travel advisory for China, its highest level of caution over the rapidly spreading virus. Other countries have taken additional measures, including prohibiting foreign nationals traveling from China from entering or transiting their borders and quarantining citizens returning from China. Such sustained human-to-human viral transmission in the United States could have cascading public health, economic, and societal consequences.

While the risk of infection for Americans remained low, on January 31, 2020, the Secretary determined that, as of January 27, 2020, a public health emergency has existed in the United States as a result of confirmed cases of 2019–nCoV under section 319 of the Public Health Service Act. As part of the public health response, the President authorized temporary measures to increase the U.S. government's ability to detect and contain 2019–nCoV beginning at 5:00 p.m. EST on Sunday, February 2, 2020. Amongst these measures, U.S. citizens (and certain classes of aliens) returning to the United States who have been in Hubei Province in the previous 14 days will be subject to up to 14 days of mandatory quarantine to ensure that they received appropriate medical screening—have not contracted the virus and do not pose a public health risk—or receive proper medical care. U.S. citizens (and certain classes of foreign nationals) returning to the United States who have been in the rest of mainland China within the previous 14 days will undergo proactive entry health screening at a select number of ports of entry and up to 14 days of monitoring to ensure they have not contracted the virus and do not pose a public health risk. Pursuant to the President's proclamation, with certain exceptions, the entry of aliens who were physically present within China (excluding the Special Administrative Regions of Hong Kong and Macau) during the 14-day period preceding their entry or attempted entry into the United States has been temporarily suspended.

The CDC is closely monitoring the situation in the United States for person-to-person transmissions in the United States, is conducting enhanced entry screening at the U.S airports where travelers from China are arriving, and is enhancing its general illness response capacity at the 20 ports of entry where CDC quarantine stations are located. CDC is also supporting States in conducting contact investigations of confirmed 2019–nCoV cases identified in the United States. As of January 31, 2020, there has been at least one case of person-to-person transmission in the United States.

During Fiscal Year 2019, an average of more than 14,000 people traveled to the United States from China each day, via both direct and indirect flights. With such numbers, it would put a severe strain on the CDC to require it to both actively monitor all of these travelers and actively contain and arrange care for individuals at risk in the United States. This continues to be the case, even with the temporary travel restrictions, given the scope of the public health response in which CDC is engaged. The virus has spread to 28 countries, including Germany, Japan, Taiwan, and Vietnam, among other countries, and as of February 1, 2020, there were 8 confirmed cases in the United States.

II. Newly Required Data Reporting

By this interim final rule, CDC requires airlines to collect, and within 24 hours of an order by the Director of CDC, submit to CDC certain data regarding passengers and crew arriving from foreign countries for the purposes of health education, treatment, prophylaxis, or other appropriate public health interventions, including travel restrictions.

Need for Contact Data for Public Health Follow-Up

Among the fundamental components of the public health response to the report of a person with a communicable disease is the identification and evaluation of those who may have been exposed. Thus, in order to control the introduction, transmission, and spread of communicable diseases into the United States, such as 2019–nCoV, CDC must be able to identify and locate persons arriving in the United States from a foreign country who may have been exposed to a communicable disease abroad. Another fundamental component of a public health response is identifying and contacting those individuals who may have come in contact with a person with a communicable disease and who may be at risk of contracting the disease as a result of their interactions with such affected persons. The identification and notification of those exposed is an essential first step in providing the exposed access to potentially life-saving medical screening, follow-up, disease prevention measures, including vaccination and other preventive treatments, and medical treatment and supportive care. Preventing secondary cases among contacts, in turn, helps prevent the propagation and spread of disease within the community. Therefore, travelers and the public at large derive direct benefit from a system that ensures that, if an exposure has occurred, health authorities can identify, locate, and notify affected passengers and those individuals who came into contact with them within the incubation period of the disease. Contact tracing is effective at reducing cases of communicable disease at the early stages of a potential outbreak if the contacts are notified as soon after initial exposure as possible. If an efficient contact system is not in place when the first ill passengers arrive, the benefits of the contact tracing are greatly diminished.

CDC, in partnership with State, local, and international public health partners, frequently conducts contact investigations for diseases such as tuberculosis, measles, meningitis, rubella, and viral hemorrhagic fevers. The delays experienced by CDC in collecting, analyzing, processing, and sending information related to ill and exposed travelers to State and local partners have at times been significant, sometimes over several days. Such delays may prevent CDC and State and local partners from providing timely public health interventions designed to educate travelers and prevent additional

transmission. This interim final rule will enable CDC to receive the most useful forms of data in a more timely manner and enable it to more effectively provide critical public health services.

Based on CDC's experience, in order to conduct effective contact tracing of individuals who may be arriving in the United States from abroad, it is critical to have the person's full name, address in the U.S., one or two phone numbers, and email address. In the past, CDC has reviewed the effectiveness of different means of contacting a person. If public health authorities had a valid phone number, the contact rate is between 91 and 100 percent. With only the address, the contact rate plummets to 44 percent. With only the name—currently, a common situation—the contact rate is only eight percent. HHS and CDC have found that a phone number will allow rapid contact with an individual and can substantially improve the public health response to an outbreak. Two phone numbers increase the chance of contacting an individual, even when he or she is traveling. HHS and CDC believe that collecting email addresses will further increase the chance of contacting a person when he or she is traveling. Moreover, especially in an outbreak where CDC and its public health partners will need to conduct a significant amount of contact tracing as quickly as possible, it is critical for CDC to receive the information in a usable electronic form, so that it is easy to process, analyze, and, as necessary, transmit to its public health partners at the State and local levels of government.

By this interim final rule, CDC requires airlines to collect and submit via electronic means to CDC, beginning within 24 hours of an order from the Director, certain data regarding passengers and crew arriving on flights arriving in the United States from foreign countries. CDC believes that this is the only mechanism by which it can efficiently obtain the information it needs for a public health response to outbreaks of communicable disease and that current regulatory requirements are not sufficient, especially in public health emergencies. CDC will exercise enforcement discretion where appropriate. We note that implementation of this interim final rule will entail technical and logistical difficulties for airlines. We are confident that all airlines will make every effort to comply with it. CDC, and the Department of Health and Human Services (HHS) more broadly, will in the exercise of its enforcement discretion take into account the good faith attempts at compliance of any airline which may have difficulty in implementing the interim final rule in a timely fashion.

Currently, 42 CFR 71.20 permits the Director to require individuals to provide contact information as part of public health prevention measures. However, while 42 CFR 71.20 provides the Department with what in many instances are useful authorities, it is not in all cases adequate to address public health emergencies: It would require collection of the information from a large number of individuals, and it does not require a format. Hence, the information may be effectively unusable—thousands of pages of paper documents in non-standardized formats. Thus, it would be inefficient and cumbersome to obtain, organize, review, and appropriately disseminate such information from thousands of individuals, particularly during a public health emergency when time is of the essence. It is more efficient to collect such information from airline carriers, whose numbers are more limited. Moreover, while it might be theoretically possible to collect contact information directly from airline passengers, such a collection—unless conducted at all times for all passengers—would inevitably mean that CDC would not have information to conduct contact tracing and public health follow-ups for those individuals who were on flights at the beginning of or before an outbreak.

In an outbreak, paper records (such as those collected during public health screening programs at ports of entry) and paper customs declarations are inadequate for contact tracing or public health follow-ups. Moreover, customs declarations are not being collected and stored consistently for all travelers at this time, and in some airports they are not required for U.S. travelers. As it is impossible to predict outbreaks, and given that the information from the earliest affected flights would be critical, the ability to obtain information that is continuously collected in an electronic format is extremely useful for responding to the ever-changing disease threat.

CDC's current regulations at 42 CFR 71.4, relating to the transmission of airline passenger, crew, and flight information for public health purposes, specify that airlines ''must provide certain information to CDC to the extent that *such data are already available and maintained* [. . .].'' 42 CFR 71.4(a) (emphasis added).[3] However, such data are not always ''already available and maintained.'' Accordingly, even with the current requirements, CDC sometimes receives information that is not timely, complete, or accurate. The Department of Homeland Security has attempted to help CDC fill the gaps in these data in order to try and make contact with exposed travelers in a timely manner. However, even with this assistance, gaps can still remain and acquiring contact information for large numbers of incoming travelers, as needed during the current response to 2019–nCoV, can rapidly become impracticable.

Under this interim final rule, CDC envisions that information will be provided by carriers and shared with CDC using the procedures currently in effect with respect to data that is provided to CDC pursuant to 42 CFR 71.4. Specifically, DHS will assist HHS in facilitating the transmission of the requested information using the existing data-sharing infrastructure in place between HHS and DHS. These infrastructures already have operationalized safeguards for data privacy and security. And CDC will hold any received data under current protocols for data privacy and security for information obtained under 42 CFR 71.4(a) and (b).

Provisions of the Interim Final Rule

Given the limitations associated with the current regulatory requirements, CDC is exercising its statutory authority to require any airline with a flight arriving into the United States, including any intermediate stops between the flight's origin and final destination, to collect and, within 24 hours of an order by the CDC Director, transmit to CDC the following five data elements with respect to each passenger and crew member who may be at risk of exposure to a communicable disease, to the extent that such information exists for the individual, and in a format acceptable to the Director:

1. Full name;
2. Address while in the United States;
3. Email address;

[3] These data elements are (1) full name (last, first, and, if available, middle or others); (2) date of birth; (3) sex; (4) country of residence; (5) if a passport is required, passport number, passport country of issuance, and passport expiration date; (6) if a travel document other than a passport is required, travel document type, travel document number, travel document country of issuance and travel document expiration date; (7) address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S. (number and street, city, State, and zip code); (8) primary contact phone number to include country code; (9) secondary contact phone number to include country code; (10) email address; (11) airline name; (12) flight number; (13) city of departure; (14) departure date and time; (15) city of arrival; (16) arrival date and time; and (17) seat number. 42 CFR 71.4(b).

4. Primary phone number; and
5. Secondary phone number.

These are the pieces of data most useful for CDC and provide the agency and its partners with a capability to provide critical public health services.

In order for CDC to perform its critical public health functions with respect to an outbreak of a communicable disease, the timely provision of information from the airlines is critical. But the airlines currently do not always provide such information in a timely fashion. For routine contact investigations performed during business hours without CDC surge staff, CDC experience suggests that, following a flight, it takes airlines up to seven days to respond to a single request for passenger manifest information currently collected. In addition, there is significant time and labor needed (typically several business days) for CDC to obtain additional information and process the received information into a format suitable for distribution to local health authorities in the U.S. As a result, obtaining contact information after a flight—assuming the information is available and recognizing its limitations—leads to a delay of nearly two weeks before health authorities can make the first contact. Two weeks is ample time for travelers to be lost to follow-up, or become symptomatic or infectious. The time required and costs incurred increase exponentially with multiple requests.

The required collection of this information by the airlines finds strong support in public opinion. While a significant number of air passengers expressed concerns with increased reservation or check-in time, a Harvard School of Public Health study, Project on the Public and Biological Security, found that 94% of air travelers would want public health authorities to contact them if they might have been exposed to a serious contagious disease on an airplane. In addition, 93% of domestic air travelers and 89% of international air travelers expressed a willingness to provide some type of contact information.

HHS and CDC acknowledge that coordination with other agencies reduces duplication, increases passengers' willingness to provide the information, and reduces costs to travel providers. HHS and CDC will work with all relevant departments and agencies to ensure that this process eliminates duplication with other programs and imposes the lowest cost possible on travelers and travel providers. By relying on the existing data collection and collection methods, HHS and CDC have trimmed the additional required passenger information to the minimum needed for an effective public health response. All of the data that this interim final rule requires airlines to collect and submit to CDC are data elements that the airlines are already required to submit to CDC, provided they are ordered to do so, if the data are already available and maintained. HHS and CDC also acknowledge that airlines may not currently collect all of these data and may not keep such data as they do collect in the form in which CDC would prefer to receive it. They also recognize that a certain amount of modification to airlines' information systems will be necessitated by the requirement to collect any data elements that the airlines do not currently collect from all international passengers. During this transition period, CDC anticipates working with airlines on an individual basis to ensure they are capable and able to meet the requirements of this interim final rule.

Although CDC is issuing this interim final rule, CDC continue to work with its partners to explore all avenues to obtain the information needed for a public health response to the outbreak of a communicable disease, such as 2019–nCOV.

III. Statutory Authority

The primary legal authority supporting this rulemaking is section 361 of the Public Health Service Act, 42 U.S.C. 264. Section 361, among other things, authorizes the Secretary of HHS to make and enforce such regulations as in the Secretary's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the states or possessions of the United States and from one state or possession into any other state or possession.

Section 361(a), 42 U.S.C. 264(a), states that the Secretary may make and enforce regulations as necessary to prevent the introduction, transmission, and spread of ''communicable diseases'' from foreign countries into the United States or from one state or possession (U.S. territory) into any other state or possession (U.S. territory). By its terms, subsection (a) does not seek to limit the types of communicable diseases for which regulations may be enacted, but rather applies to all communicable diseases that may impact human health. Section 361(a) further authorizes the Secretary to promulgate and enforce a variety of public health regulations to prevent the spread of these communicable diseases, including inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be sources of dangerous infection to human beings, and other measures.

In addition to section 361, HHS believes that the following Public Health Service Act sections are also relevant with respect to this rulemaking: Section 311, 42 U.S.C. 243; section 362, 42 U.S.C. 265; section 365, 42 U.S.C. 268; and section 367, 42 U.S.C. 270. Section 311 authorizes the Secretary to accept state and local assistance in the enforcement of quarantine rules and regulations and to assist states and their political subdivisions in the control of communicable diseases. Section 365 provides that it shall be the duty of customs officers (*e.g.,* U.S. Customs and Border Protection officers) and of U.S. Coast Guard officers to aid in the enforcement of quarantine rules and regulations. Section 367 authorizes the application of certain sections of the Public Health Service Act and promulgated regulations (including penalties and forfeitures for violations of such sections and regulations) to air navigation and aircraft to such extent and upon such conditions as deemed necessary for safeguarding public health.

As prescribed in section 368, 42 U.S.C. 271, and under 18 U.S.C. 3559 and 3571(c), criminal sanctions exist for violating regulations enacted under sections 361 and 362, 42 U.S.C. 264 and 265. 18 U.S.C. 3559 defines an offense (not otherwise classified by letter grade) as a ''Class A misdemeanor'' if the maximum term of imprisonment is ''one year or less but more than six months.'' 18 U.S.C. 3571 provides that individuals found guilty of an offense may be sentenced to a fine. Specifically, an individual may be fined ''not more than the greatest of''—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in death, not more than $250,000; or (3) for a Class A misdemeanor that does not result in death, not more than $100,000. Similarly, an organization found guilty of an offense may be fined ''not more than the greatest of''—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in a death, not more than $500,000; or (3) for a Class A misdemeanor that does not result in death, not more than $200,000. 42 U.S.C. 271 sets forth statutory penalties of up to 1 year in jail and a fine of $1,000. Therefore, it is classified as a Class A misdemeanor under 18 U.S.C. 3559. Because the alternate fines set forth under 18 U.S.C. 3571 are greater than the $1,000 set forth under 42 U.S.C. 271 (which sets a maximum penalty of not more than $1,000 or one

year of jail, or both for violation of quarantine laws), and because 42 U.S.C. 271 does not exempt its lower penalties from 18 U.S.C. 3571(e), the greater penalties of 18 U.S.C. 3571(b)(5) and (c)(5) apply.

IV. Request for Comment

HHS and CDC request comment on all aspects of this interim final rule, including its likely costs and benefits and the impacts that it is likely to have on the public health, as compared to the current requirements under 42 CFR 71.4. They are particularly interested in comments on:

- The extent to which airlines currently collect, with respect to passengers on inbound international flights, the data elements that this interim final rule requires airlines to collect and submit to CDC.
- When reporting is required, the time period within which airlines should be required to report such data, and whether that time period should be measured from the published time of departure or of arrival.
- Whether the Director's authority to require the reporting of the data elements listed in paragraph (e) should be limited to circumstances in which the Secretary has determined, under section 319 of the Public Health Service Act, 42 U.S.C. 247d, that a public health emergency exists, or some other public health determination. If so, should the regulation authorize the Director to require the submission of data for persons on inbound international flights that were completed prior to the issuance of the directive? If so, to what period of time prior to the directive should the Director be able to reach with this data submission requirement?

Any comments submitted in response to this interim final rule will be considered in the preparation of a final rule.

V. Rationale for Issuance of an Interim Final Rule With Immediate Effectiveness

Agency rulemaking is governed by section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553. Section 553(b) requires that, unless the rule falls within one of the enumerated exemptions, the Department must publish a notice of proposed rulemaking in the **Federal Register** that provides interested persons an opportunity to submit written data, views, or arguments, prior to finalization of regulatory requirements. Section 553(b)(3)(B) of the APA authorizes a department or agency to dispense with the prior notice and opportunity for public comment requirement when the agency, for ''good cause,'' finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

As noted above, although China has taken unprecedented steps to help control the virus, these steps have not stopped the virus from spreading outside of China into other countries, including the United States. During Fiscal Year 2019, an average of more than 14,000 people traveled to the United States from China each day, via both direct and indirect flights. That travel has decreased since the onset of the 2019–nCoV outbreak in China, and the U.S. government has taken steps to limit travel to the United States from China by aliens. Nevertheless, given the demands on its resources by the public health response to the current outbreak, CDC is experiencing difficulty in both actively monitoring travelers from China, and other countries with individuals infected with 2019–nCoV, and actively containing and arranging care for individuals at risk in the United States. The virus has caused severe illness and sustained person-to-person spread in China, and the United States reported the first confirmed instance of person-to-person spread with this virus on January 30, 2020. The goal of the ongoing U.S. public health response is to contain this outbreak and prevent sustained spread of 2019–nCoV in this country. HHS and CDC have determined that, given the exigent and rapidly emerging circumstances associated with the 2019–nCoV outbreak, it would be impracticable and contrary to the public health and, thus, to the public interest, to delay putting these provisions in place until a full public notice-and-comment process is completed.

Pursuant to 5 U.S.C. 553(b)(3)(B), and for the reasons stated above, HHS and CDC therefore conclude that there is good cause to dispense with prior public notice and the opportunity to comment on this rule before finalizing this rule. For the same reasons, HHS and CDC have determined, consistent with section 553(d) of the APA, that there is good cause to make this interim final rule effective immediately upon filing at the Office of the Federal Register.

VII. Regulatory Impact Analysis

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This interim final rule has been determined to be significant for the purposes of Executive Orders 12866 and 13563, and has been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule, or a final rule pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)–(6). The requirement does not apply if the head of the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' *Id.* section 605(b). The agency must, however, publish the certification in the **Federal Register** at the time of publication of the

rule, ''along with a statement providing the factual basis for such certification.'' *Id.* If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the **Federal Register** at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).[4] For the reasons set forth in this document pertaining to the outbreak and rapid spread of the 2019–nCoV, the Secretary finds that this interim final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 impracticable. HHS and CDC will assess the potential economic effects of this action on all small entities. Based on that assessment, HHS and CDC will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 13771

The White House issued Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This rule is not subject to Executive Order 13771, because it relates to a national security function of the United States as defined in OMB M–17–21, *Guidance Implementing Executive Order 13771, Titled* ''*Reducing Regulation and Controlling Regulatory Costs*''.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), 2 U.S.C. 1532, requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $154 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Department has determined that this interim final rule is not expected to result in expenditures by State, local, and tribal governments, or by the private sector, of $154 million or more in any one year. Accordingly, the Department has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

National Environmental Policy Act (NEPA)

The Department has determined that the amendments to 42 CFR part 71 will not have a significant impact on the human environment.

Executive Order 12988: Civil Justice Reform

The Department has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this final rule meets the standard in the Executive Order.

Executive Order 13132

This rule has been reviewed under Executive Order 13132, Federalism. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. The longstanding provision on preemption in the event of a conflict with Federal authority, 42 CFR 70.2, is left unchanged by this rulemaking. Additionally, there are no provisions in this regulation that impose direct compliance costs on State and local governments. Therefore, the Department believes that the rule does not warrant additional analysis under Executive Order 13132.

Plain Language Act of 2010

Under the Plain Language Act of 2010 (Pub. L. 111–274, October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

Congressional Review Act

The Congressional Review Act defines a ''major rule'' as ''any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.'' 5 U.S.C. 804(2). OIRA has determined that this interim final rule is not likely to result in an annual effect of $100,000,000 or more and is not otherwise a major rule for purposes of the Congressional Review Act.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Department has determined that this interim final rule will not have an impact on family well-being, as defined in the Act.

Paperwork Reduction Act of 1995

CDC currently has an approved Airline Traveler Information Collection (42 CFR part 71) (0920–1180 expires 05/31/2020), which covers its current collection of information from airlines under 42 CFR 71.4(a). The Office of Management and Budget has determined there is no new information collection requiring a submission of a

[4] An agency head may delay the completion of the regulatory impact analysis requirements for a period of not more than 180 days after the date of publication in the **Federal Register** of a final rule by publishing in the **Federal Register**, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with such requirements impracticable. If the agency has not prepared a final regulatory analysis within 180 days from the date of publication of the final rule, the RFA provides that the rule shall lapse and have no effect and shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency. 5 U.S.C. 608(b).

new information collection request under the Paperwork Reduction Act, (44 U.S.C. Chapter 35).

List of Subjects in 42 CFR Part 71

Apprehension, Communicable diseases, Conditional release, CDC, Ill person, Isolation, Non-invasive, Public health emergency, Public health prevention measures, Qualifying stage, Quarantine, Quarantinable Communicable Disease.

For the reasons set forth in the preamble, the Department of Health and Human Services, on behalf of the Centers for Disease Control and Prevention, amends 42 CFR part 71 as follows:

PART 71—FOREIGN QUARANTINE

■ 1. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 2. Amend § 71.4 by adding new paragraphs (d) and (e) to read as follows:

§ 71.4 Requirements relating to the transmission of airline passenger, crew, and flight information for public health purposes.

* * * * *

(d) Notwithstanding paragraph (a) of this section, any airline with a flight arriving into the United States, including any intermediate stops between the flight's origin and final destination, shall collect and, within 24 hours of an order by the Director, transmit to the Director the data elements in paragraph (e) of this section, in a format acceptable to the Director, for the passengers or crew who may be at risk of exposure to a communicable disease, for the purposes of public health follow-up, such as health education, treatment, prophylaxis, or other appropriate public health interventions, including travel restrictions.

(e) The data elements referred to in paragraph (d) of this section include, to the extent that such information exists for the individual:

(1) Full name (last, first, and, if available, middle or others);

(2) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S. (number and street, city, State, and zip code);

(3) Primary contact phone number to include country code;

(4) Secondary contact phone number to include country code; and

(5) Email address.

Dated: February 6, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–02731 Filed 2–7–20; 8:45 am]

BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 19–3; FCC 19–127; FRS 16411]

Reexamination of the Comparative Standards and Procedures for Licensing Noncommercial Educational Broadcast Stations and Low Power FM Stations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts changes to its rules and procedures to select and license competing applications for new noncommercial educational (NCE) broadcast stations and low power FM (LPFM) stations. The changes are designed to improve the comparative selection procedures, reduce confusion among future applicants, expedite the initiation of new service to the public, and eliminate unnecessary applicant burdens.

DATES: Effective April 13, 2020, except for rule changes to §§ 73.865, 73.872, 73.7002(c), 73.7003, and 73.7005. The Commission will publish a separate document in the **Federal Register** announcing the effective date of these rules.

FOR FURTHER INFORMATION CONTACT: Albert Shuldiner, Chief, Media Bureau, Audio Division, (202) 418–2721; Lisa Scanlan, Deputy Division Chief, Media Bureau, Audio Division, (202) 418–2704; Amy Van de Kerckhove, Attorney Advisor, Media Bureau, Audio Division, (202) 418–2726. For additional information concerning the Paperwork Reduction Act (PRA) information collection requirements contained in this document, contact Cathy Williams at 202–418–2918, or via the internet at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order (*R&O*), MB Docket No. 19–3; FCC 19–127, adopted on December 10, 2019, and released on December 11, 2019. The full text of this document is available electronically via the FCC's Electronic Document Management System (EDOCS) website at *http://fjallfoss.fcc.gov/edocs_public/* or via the FCC's Electronic Comment Filing System (ECFS) website at *http://www.fcc.gov/ecfs.* (Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.) This document is also available for public inspection and copying during regular business hours in the FCC Reference Information Center, which is located in Room CY–A257 at FCC Headquarters, 445 12th Street SW, Washington, DC 20554. The Reference Information Center is open to the public Monday through Thursday from 8:00 a.m. to 4:30 p.m. and Friday from 8:00 a.m. to 11:30 a.m. The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW, Room CY–B402, Washington, DC 20554. Alternative formats are available for people with disabilities (braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Paperwork Reduction Act of 1995 Analysis

This document contains new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, *see* 44 U.S.C. 3507. The Commission, as part of its continuing effort to reduce paperwork burdens, will invite the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document in a separate **Federal Register** Notice, as required by the PRA. These new or modified information collections will become effective after the Commission publishes a document in the **Federal Register** announcing such approval and the relevant effective date.

In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Congressional Review Act

The Commission will send a copy of this *R&O* to Congress and the Government Accountability Office (GAO) pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).