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IDSA
Infectious Diseases Society of America

October 14, 2016

The Honorable Dr. Tom Frieden
Director
US Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Frieden,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) for Control of Communicable Diseases: Interstate and Foreign. IDSA appreciates that the Centers for Disease Control and Prevention (CDC) is working to codify and increase transparency around the practices related to controlling communicable diseases. In today's ever more connected world, the ability to effectively and quickly respond to domestic and global outbreaks with appropriate and measured protocols strengthens our public health and biosecurity. IDSA also believes it is essential to ensure public cooperation through transparent, evidence-based policies that are well communicated and ensure fair treatment for all individuals.

Infectious diseases (ID) physicians are on the front lines of domestic and global outbreak preparedness and response, including the recent Ebola virus outbreak in West Africa. ID physicians also routinely deal with outbreaks of other diseases that can require quarantine, such as tuberculosis, as well as extraordinary cases like Ebola virus infections. While IDSA is enthusiastic about many of the proposed changes outlined in the NPRM, there are a few sections for which we recommend adjustments to help ensure optimal outcomes. Further, IDSA believes the NPRM should more clearly address the treatment of minors suspected of infection and minors whose parents or guardians are suspected of infection. We are pleased to offer our specific recommendations below, and look forward to further opportunities to assist the CDC in your efforts to further refine this important policy.

Section 70.1 GENERAL DEFINITIONS

ELECTRONIC OR INTERNET-BASED MONITORING—IDSA recommends that CDC clarify that the monitoring described in this policy would be conducted and utilized for healthcare purposes only and would not be used or shared for other purposes in order to ensure the safety and privacy of those being monitored.

ILL PERSONS—IDSA recommends changes for two of the definitions under this section.

> 2. Skin rash—IDSA recommends striking portions of the definition and including additional language (noted in italics) to ensure that this term fully encompasses the range of potential skin rash symptoms:
> "The individual has areas on the skin *that are red or purple, flat or bumps*; with multiple red bumps; red, flat spots; or blister-like bumps filled with fluid or pus that are intact, *draining*, or partly crusted over; *or dry and scaling patches*. The rash may be discrete or may run together, and may include one area of the body, such as the face, or more than one area."

INDIGENT—IDSA is concerned about how the indigent designation may be determined and applied, especially in regards to travelers from foreign countries. As the NPRM is currently drafted, the designation would be based upon income alone, without consideration of other factors like insurance status or foreign traveler status. IDSA supports fair and equal treatment for all individuals and is concerned that the NPRM's attempt to distinguish between indigent and non-indigent patients may lead to confusion and unequal treatment.

MEDICAL EXAMINATION—In order to protect the privacy of impacted individuals, IDSA recommends that the NPRM explicitly state that the collection of human biological laboratory samples will be used only for the diagnosis of the communicable disease that poses the current public health threat, and not for other purposes without explicit consent of the individual.

QUALIFYING STAGE—IDSA is satisfied with the definition as it is currently stated, but recommends that the policy also include language acknowledging that because different diseases have different transmission patterns, the qualifications for isolation and quarantine may differ from disease to disease and a one-size-fits-all protocol may therefore not be appropriate.

SECTION 70.5 REQUIREMENTS RELATING TO TRAVELERS UNDER A FEDERAL ORDER OF ISOLATION, QUARANTINE, OR CONDITIONAL RELEASE

For the purposes of transparency, IDSA requests that the CDC provide greater detail on policies and procedures for individuals who are denied travel permits. Specifically, it would be helpful to understand any arrangements made regarding such individuals' room and board, loss of work, and extra transportation costs. Further, IDSA encourages CDC to consider a maximum time allowance for CDC to respond to an appeal from a citizen issued a denial.

SECTION 70.6 APPREHENSION AND DETENTION OF PERSONS WITH QUARANTINABLE COMMUNICABLE DISEASES

The NPRM would allow for the apprehension and detention of individuals in the qualifying stage of a communicable disease requiring quarantine. As noted above, IDSA is concerned that an overly broad definition of qualifying stage that is not tailored to the specific disease of public health concern can place limits on the ability of healthcare workers and healthcare facility staff to appropriately respond to public health emergencies and conduct routine patient care and public health activities. For some diseases, such as Ebola virus infection, asymptomatic individuals cannot transmit the disease. In such instances, requiring a quarantine or limiting movement serves no purpose other than to limit facilities' ability to respond to these public health emergencies and to discourage otherwise willing healthcare workers from assisting. In the example of the case of Ebola virus infection in Dallas, almost 200 people were restricted from travel via commercial conveyance, with over 50 healthcare workers prevented from providing direct patient care and almost 100 prevented from working.

SECTION 70.10 PUBLIC HEALTH PREVENTION MEASURES TO DETECT COMMUNICABLE DISEASE

IDSA recommends that the NPRM specify that individuals undergoing a public health risk assessment only be asked to provide contact tracing information if the risk assessment leads to a reasonable belief that the individual may have become infected. We also ask that CDC clarify what qualifying criteria would trigger the non-invasive monitoring of passengers in line to board an aircraft.

SECTION 70.12 MEDICAL EXAMINATIONS

IDSA greatly appreciates CDC's effort to make policies regarding medical examinations more transparent and believes this effort will help immensely when communicating the need for individuals to undergo medical examination. However, IDSA recommends that a Federal order only be necessary before a medical examination if the person refuses to undergo the examination voluntarily. Requiring an order prior to all examinations could cause an undue time burden on individuals awaiting examination.

IDSA would also like to underscore the importance of providing medical examinations and determining whether an individual has a communicable disease in a very timely fashion. Persons under investigation are also at risk for delayed diagnoses for other possible diseases due to the level of precautions being taken to deal with the disease of public health concern. For example, a suspected Ebola virus infection can hinder the performance of an exam due to the use of full personal protective equipment (PPE) and significantly delay lab results due to lab refusal to examine specimens until the disease of concern has been ruled out.

SECTION 70.13 PAYMENT FOR CARE AND TREATMENT

ID physicians, patients, and hospitals have encountered problems with HHS/CDC being the payer of last resort. Patients, physicians, and healthcare facilities have encountered significant delays in payment caused by a lack of

clarity regarding which budget within CDC or state or local health departments should cover the expense. IDSA urges CDC to promulgate clearly the responsibility for this issue. One suggestion would be for a designated government entity to cover screenings and initial medical examinations for all patients under federal orders, with subsequent treatment going through the normal insurance process.

SECTION 70.14 REQUIREMENTS RELATING TO ISSUANCE OF A FEDERAL ORDER FOR QUARANTINE, ISOLATION, OR CONDITIONAL RELEASE

In addition to the information the NPRM specifies should be included in federal orders for quarantine, isolation or conditional release, IDSA believes any written orders to an individual or group should include estimates of the duration of the imposed measures, as well as the anticipated steps being taken and actions required to end the order.

SECTION 70.15 MANDATORY REASSESSMENT OF A FEDERAL ORDER FOR QUARANTINE, ISOLATION, OR CONDITIONAL RELEASE

IDSA recommends that initial reassessment be done by no later than the 72-hour mark outlined in the NPRM if at all possible. This timeline will suffice for a majority of situations, though there are circumstances in which extending the timeline by an additional 72 hours may be prudent. IDSA also acknowledges that the exact timing of these reassessments can and should vary depending on the nature of the disease of public health concern.

SECTION 70.16 MEDICAL REVIEW OF A FEDERAL ORDER FOR QUARANTINE, ISOLATION, OR CONDITIONAL RELEASE

It is unclear how non-indigent foreign travelers will be handled if they are unable to choose a medical representative. Further, it is unclear how the federal government intends to address the potential conflict of interest if the medical reviewer is also a federal government employee. IDSA strongly believes that it is imperative that the government provides adequate care and housing to anyone going through the quarantine, isolation, or conditional release process.

SECTION 70.18 AGREEMENTS

IDSA is pleased that HHS and CDC are seeking the voluntary approval of public health measures with individuals through use of a formal agreement. This should engender good will and trust with the public as well as increase transparency. We recommend that the content of the agreements be stated more explicitly. The agreement should be presented in lay language that can be easily translated into the preferred language of the individual. Further, IDSA encourages the CDC to use different terminology, such as “formal understanding” rather than “agreement” to alleviate any potential confusion that could be caused by the fact that HHS and CDC may still exercise authority, even if an individual does not enter into an agreement.

SECTION 71

Given the similarities between the two sections, please refer to IDSA’s Section 70 for comments on sections that overlap with parts of Section 71, all differences will be noted below.

SECTION 71.4 REQUIREMENTS RELATING TO COLLECTION, STORAGE, AND TRANSMISSION OF AIRLINE PASSENGERS, CREW, AND FLIGHT INFORMATION FOR PUBLIC HEALTH PURPOSES

IDSA is encouraged by this effort, as the collection of additional information and strengthening communication can be extremely helpful for contact tracing. Contact tracing is one of the most important mechanisms for containing an outbreak and reducing exposure to diseases of public health concern. Many ID physicians have first-hand experience contact tracing for outbreaks of tuberculosis, measles, and much more. When dealing with communicable diseases in a public health emergency setting, time is your most valuable asset, and being able to identify everyone that an infectious individual may have come into contact with quickly and efficiently can potentially prevent dozens of infections. Making the changes HHS/CDC has outlined in this section will have an important impact on these efforts.

SECTION 71.5 REQUIREMENTS RELATING TO COLLECTION, STORAGE AND TRANSMISSION OF VESSEL PASSENGER, CREW, AND VOYAGE INFORMATION FOR PUBLIC HEALTH PURPOSES:

See Section 71.4 comment.

SECTION 71.20 PUBLIC HEALTH PREVENTION MEASURES TO DETECT COMMUNICABLE DISEASE

IDSA is strongly supportive of all efforts that will help facilitate more effective contact tracing.

SECTION 71.33 PERSONS: ISOLATION AND SURVEILLANCE

IDSA supports the use of these new electronic technologies to better implement and monitor quarantines and isolations. Such technology already proved to be invaluable during the Ebola virus traveler monitoring program.

SECTION 71.36 MEDICAL EXAMINATIONS

See Section 70.12 comment.

SECTION 71.38 MANDATORY REASSESSMENT OF A FEDERAL ORDER FOR QUARANTINE, ISOLATION, OR CONDITIONAL RELEASE

See Section 70.15 comment.

SECTION 71.39 MEDICAL REVIEW OF A FEDERAL ORDER FOR QUARANTINE, ISOLATION, OR CONDITIONAL RELEASE

See Section 70.16 comment.

SECTION 71.40 AGREEMENTS

See Section 70.18 comment.

Once again, IDSA greatly appreciates your tremendous commitment to strengthening public health responses to communicable diseases in a way that clearly communicates the process and protocols to the public. Your leadership can drive the policy changes needed to protect public health and save lives. IDSA is grateful for the opportunity to work with you on these important efforts. Should you have any questions, please feel free to contact Colin McGoodwin, IDSA's Program Officer for Public Health Policy at cmcgoodwin@idsociety.org.

Sincerely,

Johan S. Bakken MD, PhD

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President, IDSA