

Docket No. CDC-2016-0068

BEFORE

THE UNITED STATES OF AMERICA

Department of Health and Human Services

Center for Disease Control and Prevention (CDC)

COMMENTS by

NATIONAL HEALTH FREEDOM ACTION

**Requesting the Withdrawal of the CDC's Notice of Proposed
Rulemaking entitled:**

Control of Communicable Disease

NHFA – Who we are.

National Health Freedom Action (NHFA) is a 501(c) 4 non-profit corporation working to promote access to all health care information, services, treatments and products that the people deem beneficial for their own health and survival as well as promoting legislative reform of the laws impacting the right to access and promoting the health of the people of this nation.¹

NHFA responds to calls year-round from individuals and groups throughout the country that wish to promote legal reform in occupational laws and regulations having to do with health care on the state level, and with federal and international product laws and regulations having to do with access to desired products. NHFA works with citizens to empower them to take action to address these concerns. NHFA educates and trains citizens on health freedom principles and on how to develop and pass proactive health freedom legislation that will ensure the rights of health care practitioners to offer their services and the rights of consumers to have access to products, practitioners, and information.

NHFA staff members draft model legislation, testify at legislative hearings and public policy meetings, and provide strategic support and lobbying assistance and often assist state leaders in developing local health freedom organizations. NHFA is a sister organization to National Health Freedom Coalition, the host for the US Health Freedom Congress and NHFA participates actively in the Health Freedom Congress and its planning.

Americans Are Aware and Concerned: There is awareness among Americans that personal choice in health care directly impacts how, and whether, a person will gain a full sense of health and wellness. In addition, Americans are deeply concerned about infringements on their ability to make choices caused by regulatory systems that do not adequately protect a person's personal liberties.

¹ National Health Freedom Action, www.nationalhealthfreedom.org/nhfa.

NHFA's Basis for Responding to the Notice of Proposed Rulemaking on Control of Communicable Disease

NHFA became aware of the Notice of Proposed Rulemaking [hereinafter NPRM] through its continual vigilance in the area of health freedom and through multiple correspondences sent to NHFA from health care practitioners, consumers, and state health freedom organizations and leaders across the country requesting an explanation of the NPRM. The correspondences NHFA received reflect mass opposition amongst readers of the NPRM. NHFA's review of the NPRM leads us to also oppose the NPRM and to conclude that it should be withdrawn in its entirety. Given NHFA's leadership role in protecting the personal liberty rights of health care consumers, NHFA is providing the following comments.

NHFA's Request for Withdrawal of the CDC NPRM for Control of Communicable Disease

The NPRM would be, if adopted, a direct and onerous infringement on the personal liberties of Americans and an unnecessary aggressive method of assisting in the control of communicable disease. NHFA recommends that the CDC withdraw the NPRM in its entirety.

NHFA's Basis for Requesting Withdrawal of the NPRM

1. **The NPRM's increased observation** measures are a drastic departure from the current policy of investigation of persons reasonably believed to be impacted by a dangerous outbreak and would deeply impact the personal liberties of all Americans.
2. **The NPRM's creation of a federal agreement option** is fraught with the potential for abuse of power and misrepresentation to individuals who will be offered this agreement option in a time of crisis and, in the long run, may make it more difficult for individuals being questioned or detained to protect their own rights to decline or make medical treatment choices if they end up under surveillance.
3. **The NPRM's recommendation to detain an individual** for up to 72 hours without a federal order of quarantine, isolation, and conditional release is an affront to personal liberties.

4. **The NPRM's proposal to add electronic collection of data systems** of personal information and electronic monitoring for those under surveillance is completely unacceptable to large numbers of Americans for privacy reasons and health reasons.

NHFA's Detailed Comments

NHFA holds that, given the detailed laws already in place giving the CDC broad rulemaking authority to prevent the introduction, transmission, and spread of communicable diseases in interstate and foreign countries into the U.S. and its broad powers to apprehend persons moving across interstate borders and entering the U.S. from international locations regarding a certain and specific number of communicable diseases^{2,3,4}, the NPRM would be an overreaching and dangerous threat to personal liberties and the health of the people of this nation and recommends that the NPRM be withdrawn.

- a. **Airline and vessel operators increased reporting requirements of ill persons:**

The CDC is attempting to move toward additional mandatory reporting by airline and

² 42 U.S.C. 264(a), Promulgation and enforcement by Surgeon General: "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

³ 42 U.S.C. 264(b), Apprehension, detention, or conditional release of individuals: "Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General."

⁴ 42 CFR 70.6, Apprehension and detention of persons with specific diseases: "Regulations prescribed in this part authorize the detention, isolation, quarantine, or conditional release of individuals, for the purpose of preventing the introduction, transmission, and spread of the communicable diseases listed in an Executive Order setting out a list of quarantinable communicable diseases, as provided under section 361(b) of the Public Health Service Act. Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at <http://www.cdc.gov/quarantine> and http://www.archives.gov/federal_register. If this Order is amended, HHS will enforce that amended order immediately and update its Web site. [77 FR 75884, Dec. 26, 2012]."

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vessel operators, by broadening their reporting requirement to include a broader definition of reportable illness.^{5,6} *Under one assumed scenario, the change in the definition of “ill person” included in the NPRM could result in a 25% increase in the number of info-only reports.*⁷ NHFA believes that this is a huge underestimate of the impact of the NPRM proposal. This change would definitely negatively impact all travelers and travel information and be invasive to the privacy of travelers, as they would be observed for illness under definitions that include the majority of common communicable illnesses, and reported on by carriers, and possibly be unnecessarily detained, as a preventive measure.

⁵ NPRM at p. 54304-05, “CDC is proposing to update the definition of ‘ill person’ by codifying current practice with the anticipated effect of better facilitating identification of communicable diseases of concern and quarantinable communicable diseases aboard flights and maritime voyages to the United States, diseases such as measles, viral hemorrhagic fevers, active tuberculosis, and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic. CDC is also proposing to include a provision to allow the Director to add new symptoms to the definition of ill person to respond to unknown communicable diseases that may emerge as future concerns.”

⁶ See Table, below, citing NPRM at p. 54305:

NHFA’s Comparison Table of Current and Proposed Definitions of Ill Person.

“The current definition of ill person, which applies to both airlines and maritime vessels, is anyone who:

- (1) Has a temperature of 100.4° F (or 38°C) or greater, accompanied by a rash, glandular swelling, or jaundice, or which has persisted for more than 48 hours; or
- (2) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of a greater than normal (for the person) amount of loose stools.”

“The proposed definition of ill person in the context of aircraft is proposed as follows:

- (a) Who if onboard an aircraft:
 - (1) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater; or feeling warm to the touch; or giving a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, or appears obviously unwell; or
 - (2) Has symptoms or other indications of communicable disease, as the CDC may announce through posting of a notice in the Federal Register.”

⁷ NPRM at p. 54267.

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The CDC's desire to "*improve HHS CDC's ability to receive reports of symptomatic interstate travelers allowing for more efficient evaluation*"⁸ stems from a valid desire to control disease, but the dramatic change from current measures to increasing the observation requirements of all carriers to report such a broad range of possibly symptoms of illness in passengers is not a rational solution in America. It is unacceptable to Americans to be observed and monitored by private carriers complying with government mandates in such personal matters and to become suspect whenever displaying possible signs of illness. It is unacceptable to Americans to be forced to share deeply personal information before being allowed to complete further travel. It is a bizarre solution not reflective of American values. There are thousands of other ways to control communicable disease without infringing on American values and privacy.

It is one thing to interview a person who is reasonably believed to be in the communicable stage of a quarantinable communicable disease and to interview 1000 persons that have been on flights exposed to that person, yet completely another to screen millions of people moving from state to state or into the U.S. for possible signs of illness that are part of daily struggles of life. Changes to the observation and reporting requirements of carriers are foundational to the NPRM's proposal. And since the definition of reportable illness is the entry point to any federal order it follows that the number of investigations as to whether a person is in a communicable stage of a quarantinable communicable disease or exposed to such will also expand. We believe that this mandatory reporting of all people who move about while displaying possible signs of illness is unfounded and can be viewed as an attempt by the government to try and control all of life and all of life outcomes, to the extent that they have lost all perspective of the ability for people to be responsible for the risks that they take in their health and with travel arrangements. In America, disease control measures must always avoid invading an individual's right of personal liberty and privacy.

b. Regarding entering into an "Agreement":

The proposal to make new rules that provide for persons to voluntarily enter into an

⁸ NPRM at p. 54236, "70.11 would improve HHS/CDC's ability to receive reports of symptomatic interstate travelers allowing for more efficient evaluation and enabling HHS/CDC to expedite its domestic response activities, (e.g. distributing Passenger Locator Forms) to more quickly and efficiently locate and assess exposed travelers, and mitigate the spread of disease."

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agreement with the federal government⁹ when detained or apprehended regarding compliance with the federal quarantine order, would create mass confusion and misrepresentation during a time of crisis. It could be viewed as a way to give the federal government documentation and assurance that a person plans to carry out the health measures with which the federal government wants him/her to comply even if that person doesn't wish to comply, and as a way to check up on him/her as he/she is in the process of quarantine, isolation and conditional release.

We believe that offering an opportunity for people to enter into a contract, or an "agreement", under these circumstances, is confusing and misleading because people may not realize the potential unintended consequences of consenting to such an agreement and that, even without an agreement, the federal order for quarantine, isolation, and conditional release would be in place and would require people to abide by it or be criminally penalized.

Upon reading the proposed rule, many Americans are questioning why the CDC would want to recommend an agreement – especially when the NPRM repeatedly states that "agreements are not a prerequisite to the exercise of the CDC's authority under this part."¹⁰

In our analysis, we are aware that under current law the federal government has authorized "...*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.*"¹¹

But we found no authority under current laws that point to the ability of the government to force treatments on people in quarantine, isolation, or conditional release. This is concerning because the proposed definition of agreement includes vaccines, treatments, and other measures.¹² We think that persons entering into these agreements would agree to undergo federally recommended health care treatments, without realizing that without

⁹ NPRM at p. 54312, "§ 70.18 Agreements. CDC may enter into an agreement with an individual, upon such terms as the CDC considers to be reasonably necessary, indicating that the individual consents to any of the public health measures authorized under this part, including quarantine, isolation, conditional release, medical examination, hospitalization, vaccination, and treatment; provided that the individual's consent shall not be considered as a prerequisite to the exercise of any authority under this part."

¹⁰ See, e.g., NPRM at p. 54249.

¹¹ 42 U.S.C. 264(a).

¹² See NPRM, p. 54249, at §70.18 Agreements.

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the agreement they would retain their rights to decline treatments; despite the claim that “agreements are not a prerequisite to the exercise of the CDC’s authority,”¹³ we do not believe forced treatments are within the CDC’s authority. People may not realize that they would be agreeing to give up their right to decline recommended treatment measures, including vaccines and other treatments. We can only imagine what such an agreement would say but, regardless, there is no mention in the NPRM or in the agreement definition of providing any notice to signers that they would be relinquishing their fundamental rights. People currently maintain the fundamental right of informed consent for all medical treatments.

Does the CDC plan to use the agreements to force vaccination and other medical treatments on people who are detained as a condition of release in addition to forcing them on those who are under quarantine, isolation and surveillance? Many Americans are very concerned that the CDC is using the NPRM to cross the line and attempt to expand the power to quarantine into the power to mandate compliance with treatment recommendations.

The CDC needs to clarify the differing impacts on personal liberty that arise when quarantining a person as compared to when treatment recommendations are made. It is noticeable that this NPRM discusses in detail vaccines, the cost of vaccines, and the recommendations.¹⁴ The focus on treatments is of great concern to many Americans unless there are clear processes to decline such treatments.

c. Regarding the Issue of “Non-invasive”:

The NPRM gives the impression that the CDC is very committed to the concept of

¹³ See, e.g., NPRM at p. 54249.

¹⁴ See, e.g., NPRM at p. 54277, TABLE 29—ESTIMATED MARGINAL COSTS FOR HEALTH DEPARTMENTS TO CONTACT EXPOSED TRAVELERS AND OFFER MEASLES POST-EXPOSURE PROPHYLAXIS (VACCINATION), 2015 USD; NPRM at p. 54272, “...*This would allow states to start their investigations more quickly, contact more travelers faster to conduct public health assessments and potentially offer preventive medications or vaccines in a more timely fashion.*”; and NPRM p. 54274, after TABLE 24—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF BENEFITS FROM INCREASED EFFICIENCIES FOR HHS/ CDC AND PHDS TO CONDUCT CONTACT INVESTIGATIONS WITH PROVISION OF BETTER DATA FROM AIRLINES, 2015 USD “... *First, exposed travelers without measles immunity may be offered post-exposure prophylaxis with measles-containing vaccine (within 72 hours) or immune globulin (within 6 days), which can prevent onset of disease, halting outbreaks before they begin. Under the status quo, relatively few exposed travelers receive post-exposure prophylaxis (just 11 out of 248 travelers with no history of measles immunization or infection).*”

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personal liberty via its inclusion of and definition of the term “non-invasive.”¹⁵ In fact, the NPRM proposes clarification of the bounds of CDC’s authority regarding what they can do to a person’s body by recommending a new definition of “*Medical Examination*.”¹⁶ But that new definition states that the CDC could order laboratory testing under certain conditions.¹⁷ Forced laboratory testing, without the option of quarantine instead, is an invasive measure; how is that in line with the concept of being non-invasive?

The CDC is highlighting “non-invasive” in their approach to detainees and includes the term “non-invasive” in the definition of “*Public Health Prevention Measure*”.¹⁸ This could lead a person to assume that the CDC does not intend to be invasive to the human body in any way. Then, however, not only is laboratory testing mentioned as part of the federal order for detaining, but vaccines and medical treatments and other measures are cited as things that would be included in agreements made to comply with federal orders. Vaccines, medical treatments and other measures are invasive. That is why the concept of signing an agreement is of great concern. Nowhere does the NPRM mention that the CDC would have the authority to force health care “vaccinations and treatments” except in the agreement language, which people would supposedly enter into voluntarily. This is a real problem that many people may not understand.

The NPRM should include strong language for detention and agreement criteria ensuring the option of non-invasiveness at all times to the human body. A contracted person, or their parent or legal guardian, should at all times be able to refuse medical treatments, including vaccines and other medical treatments, and be assured that all medical treatments and vaccines would ONLY be given after informed consent of the person

¹⁵ NPRM at p. 54309: “...procedures conducted by an authorized health worker or another individual with suitable training and includes the physical examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; auscultation; external palpation; external measurement of blood pressure; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose and mouth.”

¹⁶ NPRM at p. 54309: “*Medical examination* means the assessment of an individual by an authorized health worker to determine the individual’s health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.”

¹⁷ Id.

¹⁸ NPRM at p. 54250, “...the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual’s health status and potential public health risk to others.”

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receiving said treatment. This is an area that Americans feel very strongly about and the CDC has already received thousands of comments concerning medical and health freedom and privacy rights.

NHFA does not support the forcing of a person to undergo any bodily invasion such as laboratory testing, vaccines, or medical treatments for any reason without informed consent, and would argue that a person always maintains the right of quarantine and isolation as an option and alternative to invasion of the human body of any kind.

d. Regarding police power to detain:

Although the NPRM is addressing the transparency of CDC's existing power "*...to clarify the agency's standard operating procedures and policies with regard to existing regulations in 42 CFR parts 70 and 71 including due process rights for individuals*"¹⁹, NHFA holds that detaining an individual for up to 72 hours without a federal order of quarantine, isolation, and conditional release is completely unacceptable. It is one thing to step off a plane and be questioned for 30 minutes or two hours, to assess whether you or any person on the plane has been determined to be in a communicable stage of a quarantinable communicable disease. Yet another thing to be held in limbo overnight, and up to three overnights, waiting to see if you will be served a federal order of quarantine.

The NPRM does not discuss what the rules would be during the pre-federal order time frame, how a person might be approached, what notice and basis of authority for participating in questioning would be provided, the difference between rules of approaching someone who is ill as opposed to someone who has been unknowingly been exposed to someone who is ill. It also does not discuss the right of individuals to move about during pre-federal order time, what conditions and locations they would be held under, nor does it account for provision of reimbursement for travel interruptions or lost wages for those detained without federal order. It also does not discuss notices to be given to detained individuals that would work to strongly protect individual protection of civil liberties and individual preferences during a federal order of quarantine, isolation, and conditional release process.

If there is "reason to believe" there is a quarantinable communicable disease already in play before detaining someone, then any assessment should be able to be completed within hours and certainly within 24 hours in this highly sophisticated technological age. Due to the broad definition of illness, the massive chronic and inflammatory illnesses of the

¹⁹ NPRM at p. 54284.

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American population, and the reporting requirements for carriers being proposed, we would imagine under this plan, huge numbers of individuals being interrogated or detained daily. Having a short assessment period would therefore be essential in this large scale of a project. This specifically points out the absurdity of the project and attempting to monitor all ill people traveling and then detaining large numbers of people for up to 72 hours.

There is an important need to make it clear that the government, when pursuing quarantine, isolation, and conditional release, is to be forever vigilant of the rights of the individual, and to use the least restrictive means of detaining, apprehension, or confinement, at all times, including allowing persons to be able to be in their own home, with family, and with the type of health care treatments that they themselves deem beneficial for their health and survival. NHFA supports the transparency of due process for all citizens, including providing strong notice to persons of their civil and human rights.

e. Regarding electronic monitoring:

Adding “*the electronic collection and submission of additional passenger and crew contact information to the Advance Passenger Information System (APIS)*”²⁰ and holding in storage large amounts of personal health data on individuals for 60 days is a deeply concerning issue for Americans who care about their own personal liberty and privacy. Given large numbers of security breaches of data,²¹ Americans are becoming more conscientious about giving out their own personal information, and especially their health care data.²²

In addition, using electronic monitoring for surveillance procedures carries health concerns due to the negative health impact and injuries of electromagnetic frequencies on people’s health without the proper health standards in place.²³ The NPRM does not address the privacy or health issues regarding electronic monitoring and assumes that individuals want electronic solutions whenever possible. The NPRM should acknowledge that electronic monitoring is not acceptable to large numbers of Americans.

²⁰ NPRM at p. 54237.

²¹ See <http://www.privacyrights.org/data-breach-FAQ#6>.

²² For government information on the complexity and importance of privacy and security of health care records, see: <http://www.hhs.gov/hipaa/index.html>. See also <https://www.healthit.gov/providers-professionals/ehr-privacy-security/resources>.

²³ See BioInitiative 2012: A Rationale for Biologically-based Exposure Standards for Low Intensity Electromagnetic Radiation Standards, by Bio Initiative Working Group, available at <http://www.bioinitiative.org/table-of-contents/>.

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There is need to make sure that all electronic data sharing is only done with the approval of the individual whose records are being requested, and that he/she has the option for no data collection or sharing of his/her information in the first place. Additionally, any electronic monitoring methods used during surveillance, whether in person, conventional phone, or more electronically advanced methods, are at the detained individual's preference with written consent requirements.

In Summary

NHFA respectfully urges, and strongly encourages the Center for Disease Control and the U.S. Department of Health and Human Services, to cease any further work on the NPRM and officially withdraw it in its entirety with notice to the public based on the concerns outlined by NHFA above.

Respectfully Submitted:

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