Docket No. CDC - 2016-0068

National Vaccine Information Center

Public Comment Oct. 14, 2016

Notice of Proposed Rule Making: Control of Communicable Diseases
Published by Centers for Disease Control and Prevention (CDC)
Aug. 15, 2016 in the Federal Register

The National Vaccine Information Center (NVIC) is a 501(c)3 non-profit charity founded in 1982 to prevent vaccine injuries and deaths through public education. NVIC is the oldest and largest consumer led organization in America monitoring vaccine science, policy and law and advocating for the inclusion of vaccine safety and informed consent protections in U.S. vaccine policies and laws. NVIC co-founders were responsible for securing nationwide vaccine informing, recording and reporting safety provisions in the National Childhood Vaccine Injury Act of 1986. As an independent clearinghouse for information on vaccines, diseases and protection of civil liberties, NVIC does not make vaccine use recommendations and supports fully informed, voluntary vaccine decision-making.

Summary of NVIC's Position

On Aug. 15, 2016 a Notice of Proposed Rule Making (NPRM) was published by the U.S. Centers for Disease Control and Prevention (CDC) in the <u>Federal Register</u> amending the Public Health Service Act to codify into law when and how the federal government can "more quickly and efficiently" exercise police power to apprehend individuals or their minor children, who are entering the U.S. or traveling across state borders by airplane, ship, bus or train, and isolate or involuntarily quarantine them if they have minor symptoms of illness that could indicate "they are or may become infected with quarantinable infectious diseases." Although measles is not a disease on the current federal <u>Isolation and Quarantine</u> list, the NPRM states that, "The ongoing persistence of measles in the United States provides a good example of the need for this NPRM" and frequently references measles, chickenpox and other non-quarantinable diseases targeted by federal vaccination policies.

Health officials in the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), have more than enough authority under the U.S. Constitution and the Public Health Service Act to prevent the introduction, transmission and spread of a short list of serious communicable diseases with very high mortality rates, such as hemorrhagic fevers. However, this NPRM makes a point of equating non-quarantinable vaccine-targeted diseases, such as measles and chickenpox, with quarantinable diseases, such as tuberculosis and smallpox. It expands the list of minor illness symptoms that could trigger the use of police power by government health officials to apprehend and involuntarily quarantine individuals, who can be asked to consent to vaccination as a condition of release from government custody.

Therefore, this NPRM raises the legitimate question of whether it will be followed by a request from the Secretary of Health and Human Services for a Presidential Executive Order to expand the Isolation and Quarantine list to include measles and other vaccine targeted diseases for the purpose of apprehending and quarantining travelers entering the US or traveling between states, who have not been vaccinated with MMR (measles-mumps-rubella vaccine) and other federally recommended vaccines.

The NPRM outlines the circumstances under which an individual (or the minor child of an individual) can be taken into government custody for 72 hours without access to an attorney to appeal loss of liberty and without access to a personal physician to ensure protection of the individual's unique health, medication or dietary restriction needs and preferences, including those that involve freedom of religion and conscience. It compels the detained person to choose between an indefinite period of involuntary quarantine or signing a written contract, described by the CDC as a "public health agreement," that gives consent to the application of certain "public health measures," including vaccination and electronic tracking, in order to be set free. However, most importantly, the NPRM clearly states that, "the individual's consent shall not be considered a prerequisite to any exercise of any authority" by the CDC.

This NPRM legally requires public transportation industry personnel to conduct surveillance on travelers and make medical judgments about the appearance of fellow citizens for the purpose of reporting them as persons of interest to CDC officials. It places travelers at risk for suffering physical, mental, emotional and psychological harm, as well as financial hardship, when they are unpredictably taken into custody for simply appearing "unwell" and are subjected to involuntary quarantine by government officials because they may have been exposed to or are judged to be susceptible to a quarantinable disease.

It is un-American to detain citizens for minor illness symptoms or to involuntarily quarantine and force them to choose between losing their freedom and signing a contract with the government consenting to vaccination and other "public health measures," including electronic tracking, that could result in harm, especially when federal government employees are not legally liable in civil courts for any harm that is done. This is particularly relevant if the Isolation and Quarantine list is expanded to include measles and other diseases targeted by federal vaccine policies when vaccine manufacturers are shielded from product liability under the National Childhood Vaccine Injury Act of 1986.

This NPRM exemplifies the kind of federal government overreach that increases fear and distrust of government officials and public health policies. It places travelers at risk for physical, mental, emotional and psychological harm and financial hardship when federal health officials invoke police power in the name of disease control, violating the long-standing rule that government should respect individual autonomy and use the least restrictive means to achieve public health goals.

The National Vaccine Information Center (NVIC) opposes the NPRM and calls on the Secretary of the Department of Health and Human Services to withdraw it and for Congress to ensure that it does not become law.

Following is a more detailed referenced statement about the NPRM and NVIC's major objections to this amendment to the Public Health Service Act.

The Federal Government Has Authority to Control Serious Communicable Diseases

The CDC's Aug. 15, 2016 Notice of Proposed Rule Making (NPRM)¹ to amend the Public Health Service Act is unnecessary. Under the U.S. Constitution and the Public Health Service Act the federal government has long had the authority to exercise police

power to detain and quarantine individuals entering the U.S. or crossing state borders by air, sea or land to prevent the introduction, transmission and spread of an appropriately short list of communicable diseases with a high mortality rate, including yellow fever, cholera, diphtheria, infectious tuberculosis and plague.²

Based upon a recommendation from the Secretary of Health and Human Services, a 2003 Presidential Executive Order³ gave federal health officials authority to use police power to control spread of SARS and hemorrhagic fevers like Ebola, which has a mortality rate of 25 to 90 percent.⁴ A 2005 Presidential Executive Order added pandemic influenza to the federal Isolation and Quarantine list.⁵

A <u>Presidential Executive Order issued on July 31, 2014</u> did not name a specific disease that would allow federal health officials to use police power authority to detain and quarantine individuals, it simply described "diseases associated with fever and signs and symptoms of pneumonia or other respiratory illness" that have "the potential to cause a pandemic" or are "highly likely to cause mortality or serious morbidity if not properly controlled." ⁶ It is important to note that many frequently occurring communicable diseases, such as the common cold, cause fever and respiratory symptoms and almost all viral and bacterial infections have the potential to cause injury and death.

NPRM Requires Public Transportation Personnel to Report Travelers with Minor Symptoms of Illness to CDC

Although the select communicable diseases currently on the federal Isolation and Quarantine list that allow use of police power by federal officials are those with high mortality rates, this NPRM requires non-medical civilian public transportation personnel to conduct surveillance on the appearance of travelers and report those exhibiting minor symptoms of illness to the CDC. ⁷ It is clearly designed to broaden the circumstances under which an individual (or the minor child of an individual), who is traveling by airplane, ship, bus or train into the U.S. or between states, can be judged to be "unwell" by transportation industry personnel and taken into custody by the federal government, involuntary quarantined and persuaded to consent to vaccination or other "public health measures" before being released.

Although not on the Isolation and Quarantine list, the NPRM frequently refers to measles and other infectious diseases targeted by federal vaccine use policies:

- "The ongoing persistence of measles in the United States provides a good example of the need for this NPRM."
- "Every case of measles in the United States is considered a public health emergency because of its extremely high transmissibility."9

The NPRM states that, "different diseases may elicit different levels of responses at the public health department level, with a more rapid response for highly infectious diseases like measles that can be prevented with timely post-exposure prophylaxis, and a more

measured response for less infectious diseases like TB."¹⁰ The term "post-exposure prophylaxis" for a traveler, who has a rash or is considered to be at risk for contracting measles, is MMR vaccination.

In the NPRM, the CDC defines a potentially "ill" person deserving of special scrutiny by public transportation personnel and government officials to be someone with "areas of the skin with multiple red bumps, red, flat spots or blister like bumps filled with fluid or pus that are intact or partially crusted over," warning that "the presence of skin rash, along with fever, may indicate that the traveler has measles, rubella (German measles), varicella (chickenpox) meningococcal disease or smallpox." Other illness symptoms that could trigger a report to federal health officials by transportation personnel include cough, diarrhea, vomiting, abdominal cramps, headache, muscle aches, fever of 100.4 degrees F. or appearing "obviously unwell." 12

Significantly, one or more of these frequent symptoms of illness are present when people are suffering from asthma, bronchitis, inflammatory bowel disease, food poisoning, hangovers, migraine headaches, hives, acne, rosacea, eczema, psoriasis, severe allergies and the common cold. If the NPRM becomes law, observance of these symptoms by public transportation personnel could trigger arbitrary reports to the CDC followed by inappropriate apprehension of many travelers.

NPRM Allows Detention of Individuals for 72 Hours Without Appeal

The NPRM allows government health officials to use police power to apprehend and take an individual into custody for 72 hours without legal access to an attorney to appeal the detention and protect human rights. During the 72 hour detention, the individual will not have access to a personal physician to ensure protection of unique health, medication or dietary restriction needs and preferences, including those that involve freedom of religion and conscience, while the CDC "reviews" the individual's detention and quarantine. Although the CDC would allow the apprehended traveler to request a "medical review" *after* the initial 72 hours of detention, there is no access to a personal physician during detention.

During detention, the individual can be asked to sign a written contract with the government consenting to the application of "public health measures," which may include "quarantine, isolation, conditional release, medical examination, hospitalization, vaccination, and treatment." On the CDC website, federal health describe the written contract as a "public health agreement" and states that:

A public health agreement allows a traveler who may have been exposed to a quarantinable communicable disease to agree voluntarily to follow CDC instructions to prevent the spread of the disease such as to not travel, limit social contacts, or remain in isolation or quarantine. This allows a person to choose to agree to follow CDC recommendations rather than be required to comply through a public health order. Public health agreements may also include a variety of public health interventions, such as medications or vaccines offered to treat or prevent disease with the person's informed consent. Travelers who violate the

agreement in a manner that places the public's health at risk will be placed under a public health order and may face criminal charges.¹⁵

Although the CDC maintains that "the proposed rule would not authorize vaccinations, or any other medical treatment, without informed consent of the person under quarantine or isolation orders" and that "No vaccines would be administered without consent of adults or permission of parents or guardians for minors," these statements, which were published on the CDC's website on Oct. 6, 2016, contradict the text of the Aug. 15, 2016 NPRM that is the subject of this public comment. The NPRM clearly states that, "the individual's consent shall not be considered a prerequisite to any exercise of any authority" by the CDC. 17

Importantly, an apprehended traveler who refuses to give consent to the application of "public health measures," such as vaccination, can be detained in quarantine without access to an attorney or, unless indigent, without access to a medical representative to participate in a medical review of the reasons for detention and quarantine. Travelers, who request a medical review and are not indigent, will have to pay for the assistance of a personal physician or other medical professional to participate in the medical review.¹⁸

NPRM Allows Electronic Tracking of Individuals

In addition to vaccination, one of the conditions of release from quarantine is electronic monitoring of an individual's movements by federal health officials through electronic tracking devices being attached to the body or monitoring by email, cell phone texts, video conferencing and voicemail.¹⁹

NPRM Allows Criminal Prosecution, Fines, Jail

In addition, the federal government will have the authority to punish individuals violating the "public health agreement" the individual signed in order to be released from government custody. These punishments include being jailed for six months to a year and paying fines of \$100,000 to \$250,000 or, in the case of "violations by organizations," which are not explained in the NPRM, a fine of \$250,000 to \$500,000.²⁰

CDC Has Not Adequately Evaluated Federalism Implications

As the CDC points out in the NPRM, under Executive Order 13132, if rule making would limit or preempt State authorities, then a Federalism analysis is required, including consulting with State and local officials to determine whether the NPRM would have a substantial direct effect on State and local governments or preempt State law or impose direct costs on them.²¹ Although CDC states that it has determined that the NPRM "will not have sufficient Federalism implications to warrant preparation of a Federalism summary impact statement," there are enough questions about the potential use of state facilities and staff resources to isolate and quarantine travelers after detention that the CDC should be required to prepared a Federalism summary impact statement.

Under the U.S. Constitution and affirmed in U.S. Supreme Court rulings, the majority of police power that can be used to detain, isolate and quarantine citizens to control communicable diseases belongs to the states.²² ²³ Many state legislatures, which have

legal authority to pass laws controlling communicable diseases within state borders, voted to give state health officials expanded police powers after Sept. 11, 2001 by adopting the Model State Emergency Health Powers Act (MSEHPA)²⁴ ²⁵and The Turning Point Model State Public Health Act²⁶ created at Georgetown University's Center for Law and the Public's Health and the CDC Collaborating Center Promoting Health through Law.

Although the CDC operates quarantine stations at major airports to handle apprehension of travelers suspected to be infected with or at risk of becoming infected with a quarantinable disease, ²⁷ isolation and quarantine of individuals may require the participation of state health departments, medical facilities and other state resources, ²⁸ especially if more travelers are taken into custody when surveillance by public transportation personnel is increased under the NPRM.

Balancing Respect for Civil Liberties and Exercise of Police Power to Control Communicable Diseases

The controversial Model State Health Emergency Powers Act and the Turning Point Model State Public Health Act sought to rewrite state public health laws and broaden the reasons for how, why and when state public health officials could wield police power and detain, quarantine and vaccinate citizens or enforce other public health measures during declared public health emergencies. Although adopted in some form by a number of states a decade ago, the laws were a subject of considerable public criticism for unreasonably restricting civil liberties and allowing arbitrary use of force by public health officials.²⁹ This NPRM is causing controversy and public opposition for the same reason.

The need to protect civil liberties when government officials use police power to detain, isolate or quarantine citizens is becoming a frequently discussed topic in medical and law journals and for good reason.³⁰ The way that the public perceives the wisdom of public health policy and law has a direct relationship on how willing the public is to respect and follow it.³¹ ³² Arbitrary use of police power by government health officials in pursuit of public health goals will be resisted, as well as erode public trust in government.³³ This loss of trust threatens to negatively affect citizen responses during true public health emergencies when public health officials rely upon public understanding and cooperation to protect the public health and safety.

The CDC should withdraw this NPRM. It places individual travelers at risk for physical, mental, emotional and psychological harm and financial hardship when federal health officials invoke police power in the name of disease control, violating the long-standing rule that government health officials should respect individual autonomy and use the least restrictive means to achieve public health goals.

Respectfully submitted,

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