



[BILLING NUMBER: 4153-01]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 164

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the National Instant Criminal Background Check System (NICS)

AGENCY: Office for Civil Rights, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or “the Department”) is issuing this notice of proposed rulemaking to modify the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to expressly permit certain HIPAA covered entities to disclose to the National Instant Criminal Background Check System (NICS) the identities of individuals who are subject to a Federal “mental health prohibitor” that disqualifies them from shipping, transporting, possessing, or receiving a firearm. The NICS is a national system maintained by the Federal Bureau of Investigation (FBI) to conduct background checks on persons who may be disqualified from receiving firearms based on federally prohibited categories or State law. Among the persons subject to the Federal mental health prohibitor are individuals who have been involuntarily committed to a mental institution; found

incompetent to stand trial or not guilty by reason of insanity; or otherwise have been determined by a court, board, commission, or other lawful authority to be a danger to themselves or others or to lack the mental capacity to contract or manage their own affairs, as a result of marked subnormal intelligence or mental illness, incompetency, condition, or disease. Under this proposal, only covered entities with lawful authority to make adjudication or commitment decisions that make individuals subject to the Federal mental health prohibitor, or that serve as repositories of information for NICS reporting purposes, would be permitted to disclose the information needed for these purposes. This disclosure would be restricted to limited demographic and certain other information and would not include medical records, or any mental health information beyond the indication that the individual is subject to the Federal mental health prohibitor. HHS notes that the Department of Justice (DOJ) has proposed clarifications to the regulatory definitions relevant to the Federal mental health prohibitor. The DOJ proposal is published elsewhere in this issue of the Federal Register. While commenters should consider this proposed regulation in light of the clarifications proposed in DOJ's proposal, we note that those clarifications would not change how this proposed HIPAA permission would operate.

DATES: Submit comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may submit electronic comments at <http://www.regulations.gov>. Follow the instructions for submitting electronic comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.
- *Regular, Express, or Overnight Mail:* You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, *Attention:* HIPAA Privacy Rule and NICS, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW, Washington, DC 20201.
- *Hand Delivery or Courier:* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to the following address only: Office for Civil Rights, *Attention:* HIPAA Privacy Rule and NICS, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW, Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post comments received before the close of the comment period at <http://www.regulations.gov>. Because comments will be made public, they should not include any sensitive personal information, such as a person's social security number; date of birth; driver's license

number, State identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information, or any non-public corporate or trade association information, such as trade secrets or other proprietary information.

FOR FURTHER INFORMATION CONTACT: Andra Wicks, 202–205–2292.

SUPPLEMENTARY INFORMATION:

I. Background

On January 16, 2013, President Barack Obama announced 23 executive actions aimed at curbing gun violence across the nation. Those actions include efforts by the Federal government to strengthen the national background check system, and a specific commitment to “[a]ddress unnecessary legal barriers, particularly relating to the Health Insurance Portability and Accountability Act, that may prevent States from making information available to the background check system.” The National Instant Criminal Background Check System (NICS) is the system used to determine whether a potential firearms recipient is statutorily prohibited from possessing or receiving a firearm. The Department developed this NPRM to propose a modification to the HIPAA Privacy Rule to permit certain covered entities to disclose to the NICS the identities of persons who are not allowed to possess or receive a firearm because they are subject to the Federal mental health prohibitor. The Department, through this NPRM, is soliciting public input on various issues, including whether it should modify the HIPAA Privacy Rule to permit

covered entities to disclose to the NICS the identities of persons prohibited by State law from possessing or receiving a firearm for reasons related to mental health.

The National Instant Criminal Background Check System (NICS)

The Brady Handgun Violence Prevention Act of 1993, Pub. L. 103-159, and its implementing regulations, are designed to prevent the transfer of firearms by licensed dealers to individuals who are not allowed to possess or receive them as a result of restrictions contained in either the Gun Control Act of 1968, as amended (Title 18, United States Code, Chapter 44), or State law. The Gun Control Act identifies several categories (known as “prohibitors”) of individuals¹ who are prohibited from engaging in the shipment, transport, receipt, or possession of firearms, including convicted felons and fugitives. Most relevant for the purposes of this NPRM is the Federal mental health prohibitor, which, pursuant to Department of Justice (DOJ) regulations, applies to individuals who have been involuntarily committed to a mental institution, for reasons such as mental illness or drug use;² found incompetent to stand trial or not guilty by reason of insanity; or otherwise have been adjudicated by a court, board, commission, or other lawful authority to be a danger to themselves or others or unable to manage their own affairs, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease.³

¹ See 18 U.S.C. 922(g) and (n) and implementing regulations at 27 CFR 478.11 and 27 CFR 478.32.

² The regulation, at 27 CFR 478.11, defines “Committed to a mental institution” as: A formal commitment of a person to a mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily, commitment for mental defectiveness or mental illness, as well as commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution. Note that DOJ has proposed clarifications to this regulatory language, which are published elsewhere in this issue of the Federal Register.

³ The term used in the statute, “adjudicated as a mental defective,” is defined by regulation to include: “(a) A determination by a court, board, commission, or other lawful authority that a person, as a result of

The Brady Act established the NICS to help enforce these prohibitions, as well as State law prohibitions on the possession or receipt of firearms.⁴ The NICS Index, a database administered by the Federal Bureau of Investigation (FBI), collects and maintains certain identifying information about individuals who are subject to one or more Federal prohibitors and thus are ineligible to purchase firearms.⁵ As of 2012, the NICS Index also contains information on persons who are subject to State law prohibitions on the possession or receipt of firearms. The minimum information required in a NICS Index record consists of: the name of the ineligible individual; the date of birth; sex; and codes indicating the applicable prohibitor, the submitting entity, and the agency record supporting the prohibition. For individuals subject to the Federal mental health prohibitor, only the fact that the individual is subject to that prohibitor is submitted to the NICS; underlying diagnoses, treatment records, and other identifiable health information are not provided to or maintained by the NICS. A NICS background check

marked subnormal intelligence, or mental illness, incompetency, condition, or disease: (1) is a danger to himself or to others; or (2) lacks the mental capacity to contract or manage his own affairs.” The term includes a finding of insanity in a criminal case, and a finding of incompetence to stand trial or a finding of not guilty by reason of lack of mental responsibility pursuant to the Uniform Code of Military Justice. 27 CFR 478.11. Note that DOJ has proposed clarifications to this regulatory language, which are published elsewhere in this issue of the Federal Register. We also note that having “marked subnormal intelligence or mental illness, incompetency, condition, or disease,” is one necessary element of a determination that an individual (other than an individual who has been involuntarily committed) is subject to the Federal mental health prohibitor. To be subject to the Federal mental health prohibitor, such an individual also must be adjudicated to pose a danger to self or others or lack the mental capacity to contract or manage their own affairs.

⁴ See 28 CFR 25.1 through 25.11 (establishing NICS information system specifications and processes) and 27 CFR part 478 (establishing requirements and prohibitions for commerce in firearms and ammunition, including requirements related to conducting NICS background checks).

⁵ Additionally, in 2012 the NICS Index began to include the identities of persons who are prohibited from possessing or acquiring firearms by State law, which in some cases may be more restrictive than Federal law. See Statement Before the Senate Judiciary Committee, Subcommittee on Crime and Terrorism at a hearing entitled, “THE FIX GUN CHECKS ACT: BETTER STATE AND FEDERAL COMPLIANCE, SMARTER ENFORCEMENT” (November 15, 2011), by David Cuthbertson, Assistant Director, Criminal Justice Information Services Division, Federal Bureau of Investigation. Testimony available at: <http://www.justice.gov/ola/testimony/112-1/11-15-11-fbi-cuthbertson-testimony-re-the-fix-gun-checks-act.pdf>.

queries the NICS Index and certain other national databases⁶ to determine whether a prospective buyer's identifying information matches any prohibiting records contained in the databases. The NICS Index can be accessed only for the limited purposes authorized by regulation (see 28 CFR 25.6(j)) and cannot be used for other purposes, including general law enforcement activities.

The potential transfer of a firearm from a Federal Firearms Licensee (FFL) to a prospective buyer proceeds as follows: First, the prospective buyer is required to provide personal information on a Firearms Transaction Record (ATF Form 4473). Unless the prospective buyer has documentation that he or she qualifies for an exception to the NICS background check requirement under 18 U.S.C. 922(t)(3),⁷ the FFL contacts the NICS--electronically, by telephone, or through a State level point of contact--and provides certain identifying information about the prospective buyer from ATF Form 4473.⁸ Within about 30 seconds, the FFL receives a response that the prospective firearm transfer may proceed or is delayed. The transfer is delayed if the prospective buyer's information matches a record contained in one of the databases reviewed. If there is a match, a NICS examiner reviews the record to determine whether the information it contains is, in fact, prohibiting, and then either: (1) if the record does not contain prohibiting information, advises the FFL to proceed with the transaction; (2) if the record

⁶ The other databases include the Interstate Identification Index, which contains criminal history record information; and the National Crime Information Center, which includes, e.g., information on persons subject to civil protection orders and arrest warrants. Additional information is available at, <http://www.fbi.gov/about-us/cjis/nics/general-information/nics-overview>.

⁷ These exceptions are listed in the ATF regulation at 27 CFR 478.102(d). For example, a NICS check would not be required where the potential recipient of a firearm has presented a valid State permit or license, provided conditions at 27 CFR 478.102(d)(1) are met.

⁸ The form collects the prospective buyer's name; demographic information such as address, place and date of birth, gender, citizenship, race and ethnicity; and "yes" or "no" answers to questions about the person's criminal history and other potential prohibitors. The form is available at <http://www.atf.gov/forms/download/atf-f-4473-1.pdf>.

does contain prohibiting information, denies the transaction (due to ineligibility); or (3) if it is unclear based solely on the existing information in the record whether it is prohibiting, delays the transaction pending further research.⁹ The NICS examiner does not disclose the reason for the determination to the FFL (e.g., the FFL would not learn that the individual was ineligible due to the Federal mental health prohibitor). In case of a delay, if the NICS examiner does not provide a final instruction to the FFL within three business days of the initial background check request, the FFL may proceed with the transaction if it chooses to do so.¹⁰

Although FFLs are required in most cases to request a background check through the NICS before transferring a firearm to a prospective buyer,¹¹ Federal law does not require State agencies to report to the NICS the identities of individuals who are prohibited from purchasing firearms, and not all States report complete information to the NICS or the databases checked by it. Following the shooting at Virginia Tech University in 2007, and other tragedies involving the illegal use of firearms, Congress enacted the NICS Improvement Amendments Act (NIAA) of 2008, Pub. L. 110-180. Among other provisions, the NIAA requires Federal agencies to make accessible to the NICS the identities of individuals known by the agencies to be subject to one or more prohibitors, and it authorizes incentive grants for States to provide such information when it is in their

⁹ For example, a “delay” response may mean that further research is required because potentially prohibitive criteria exist, but the matched records are incomplete, See Federal Bureau of Investigation (FBI) Fact Sheet at: www.fbi.gov/about-us/cjis/nice/general-information/fact-sheet.

¹⁰ Some States have waiting periods that also must be complied with before a firearm may be transferred, regardless of whether a proceed response from NICS is received by the FFL within three business days.

¹¹ See 27 CFR 478.102. Exceptions to this requirement are referenced in FN 7 above, and listed in the regulation at 27 CFR 478.102(d).

possession.¹² In addition, some States enacted legislation requiring the reporting of the identities of ineligible individuals to databases accessible to the NICS or to a State level repository responsible for submitting information to the relevant databases. Although the States generally report criminal history and related information to the appropriate FBI-maintained databases that are checked by the NICS, many States continue to report little if any information to the NICS Index, so the NICS does not have access to complete information about all individuals who are subject to one or more of the Federal prohibited categories or prohibited from possessing or receiving firearms under State law.¹³

The HIPAA Privacy Rule and NICS Reporting

The Privacy Rule, promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Title II, Subtitle F – Administrative Simplification, Pub. L. 104-191, establishes federal protections to ensure the privacy and security of protected health information and establishes an array of individual rights with respect to one’s own health information. HIPAA applies to covered entities, which include health plans, health care clearinghouses, and health care providers that conduct certain standard transactions (such as billing insurance) electronically. HIPAA covered entities may only use and disclose protected health information with the individual’s written authorization, or as otherwise expressly permitted or required by the HIPAA Privacy Rule.

¹² Eligibility for these grants is limited to States that have implemented a relief from disabilities program for individuals who are prohibited from possessing or receiving firearms for mental health reasons. Such programs must provide that a State court, board, commission, or other lawful authority shall grant the relief if, based on the circumstances regarding the disabilities and the person’s record and reputation, the person is not likely to pose a danger to public safety, and granting the relief would not be contrary to the public interest. See Pub. L. 110-180, Section 105.

¹³ The same is true of the other two databases accessed during a NICS Check, the III and NCIC. State participation and reporting to those databases is also not required.

The Privacy Rule seeks to balance individuals' privacy interests with important public policy goals including public health and safety. In doing so, the Privacy Rule allows, subject to certain conditions and limitations, uses and disclosures of protected health information without individuals' authorization for certain law enforcement purposes, to avert a serious threat to health or safety, and where required by State or other law, among other purposes. See 45 CFR 164.512.

As stated above, individuals who are subject to the Federal mental health prohibitor are ineligible to purchase a firearm because they have been "committed to a mental institution" or "adjudicated a mental defective", 18 U.S.C. 922(g)(4). DOJ regulations define these categories to include persons who have been involuntarily committed to a mental institution for reasons such as mental illness or drug use; have been found incompetent to stand trial or not guilty by reason of insanity; or otherwise have been adjudicated by a court, board, commission, or other lawful authority to be a danger to themselves or others or unable to manage their own affairs, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease.¹⁴ Records of individuals adjudicated as incompetent to stand trial, or not guilty by reason of insanity, originate with entities in the criminal justice system, and these entities are not HIPAA covered entities. Likewise, involuntary civil commitments usually are made by court order, and thus, records of such formal commitments typically originate with entities in the justice system. In addition, many adjudications determining that individuals pose a danger to themselves or others, or are incapable of managing their own affairs, occur through a legal process in the court system.

¹⁴ As noted above, DOJ has proposed clarifications to the regulatory language relevant to these two categories; the DOJ proposal is published elsewhere in this issue of the Federal Register.

However, because of the variety of State laws, there may be State agencies, boards, commissions, or other lawful authorities outside the court system that are involved in some involuntary commitments or mental health adjudications that make an individual subject to the Federal mental health prohibitor. Moreover, we understand that some States have designated repositories to collect and report to the NICS the identities of individuals subject to the Federal mental health prohibitor. We currently do not have sufficient data to determine to what extent any of these lawful authorities or repositories also may be a HIPAA covered entity (e.g., a State health agency).

Even in circumstances where records are subject to HIPAA – for example, where the record of an involuntary commitment or mental health adjudication originates with a HIPAA covered entity, or the HIPAA covered entity is the State repository for such records -- there are ways in which the Privacy Rule permits the reporting to the NICS. In particular, the Privacy Rule permits the covered entity to disclose the information to the NICS to the extent the State has enacted a law requiring (not merely authorizing) such reporting.¹⁵ Alternatively, where there is no State law requiring reporting, the Privacy Rule permits a HIPAA covered entity that performs both health care and non-health care functions (e.g., NICS reporting) to become a hybrid entity and thus, have the HIPAA Privacy Rule apply only to its health care functions. The entity achieves hybrid entity status by designating its health care components as separate from other components, documenting that designation, and implementing policies and procedures to prevent unauthorized access to protected health information by the entity's non-covered

¹⁵ See 45 CFR 164.512(a). Note that disclosures for NICS purposes would not fall under the Privacy Rule's provisions permitting disclosures for law enforcement purposes (which apply to specific law enforcement inquiries) or to avert a serious threat to health or safety (which require an imminent threat of harm). See 45 CFR 164.512(f) and (j).

components. Thus, an entity that has designated itself a hybrid entity, in accordance with the Privacy Rule,¹⁶ can report prohibitor information through its non-HIPAA covered NICS reporting unit without restriction under the Privacy Rule.

However, many States still are not reporting to the NICS essential information on persons prohibited from possessing firearms for reasons related to mental health. Thus, concerns have been raised that the HIPAA Privacy Rule's restrictions on covered entities' disclosures of protected health information may be preventing certain States from reporting the relevant information to the NICS. Further, in July 2012, the U.S. Government Accountability Office (GAO) reported to Congress on the results of a survey of six States that it had assessed as part of a performance audit of the progress made by DOJ and the States in implementing the NIAA.¹⁷ In the report, the GAO wrote that, "... officials from 3 of the 6 States we reviewed said that the absence of explicit State-level statutory authority to share mental health records was an impediment to making such records available to NICS."¹⁸ The report also stated that, although the number of records provided by the States to the NICS had increased by 800 percent between 2004 and 2011, this increase was largely due to efforts by only 12 States. The report raised the possibility that States that do not report to the NICS the identities of individuals who are prohibited from possessing firearms for reasons related to mental health may experience challenges to reporting related to the HIPAA Privacy Rule.

II. The ANPRM

¹⁶ See 45 CFR 164.103, 164.105.

¹⁷ See GAO-12-684, Gun Control: Sharing Promising Practices and Assessing Incentives Could Better Position Justice to Assist States in Providing Records for Background Checks.

¹⁸ We note that the GAO Report uses the term "mental health records" to refer to identifying information on individuals who are subject to the Federal mental health prohibitor. To avoid implying that mental health records are collected by NICS, the Department uses the terms "identities," "information," or "data" in place of "mental health records." GAO-12-684, p. 12.

Background

On April 23, 2013, the Department published an Advance Notice of Proposed Rulemaking (ANPRM) requesting public input on these issues (78 FR 23872). The ANPRM explained that the Department was considering creating an express permission in the HIPAA Privacy Rule for reporting information relevant to the Federal mental health prohibitor to the NICS by those HIPAA covered entities responsible for involuntary commitments or the adjudications that would subject individuals to the Federal mental health prohibitor, or that are otherwise designated by the States to report to the NICS. In the ANPRM, the Department indicated that such an amendment might produce clarity regarding the Privacy Rule and help make it as simple as possible for States to report the identities of such individuals to the NICS.

The ANPRM stated that, in crafting the elements of an express permission, the Department would consider limiting the information to be disclosed to the minimum information necessary for NICS purposes, such as the names of the individuals who are subject to the Federal mental health prohibitor, demographic information such as dates of birth, and codes identifying the reporting entity and the relevant prohibitor. We indicated that the NICS does not include, and we would not consider permitting the disclosure of, an individual's treatment record or any other clinical or diagnostic information for this purpose. In addition, we would consider permitting disclosures for NICS purposes only by those covered entities that order involuntary commitments, perform relevant mental health adjudications, or are otherwise designated as State repositories for NICS reporting purposes.

To inform our efforts to address any issues in this area, we requested comments on a series of questions concerning the nature and scope of the problem of underreporting. The questions included:

- The nature and extent of States' participation in NICS reporting;
- To what extent HIPAA is perceived as a barrier to reporting, and specific examples of situations in which reporting to the NICS is hindered by HIPAA requirements;
- Steps States may have taken to address HIPAA challenges for reporting, including any statutory or regulatory changes at the State level;
- Whether States had designated any HIPAA covered agencies as repositories of information for NICS reporting purposes and, if so, how the States have addressed HIPAA requirements while reporting;
- Whether certain HIPAA covered entities in the States have authority to order involuntary commitments or perform other adjudications that make an individual subject to the Federal mental health prohibitor;
- Whether additional, non-HIPAA related barriers to reporting exist;
- Whether there are privacy protections in place for data collected for NICS reporting purposes, and whether or how State public records laws would apply to the information;
- Whether creating an express permission would have implications for treatment, and whether there would be ways to mitigate any unintended consequences of creating such a permission; and

- How HHS could disseminate information or provide additional guidance on the HIPAA Privacy Rule to address confusion about HIPAA that may affect reporting to the NICS.

We requested comments from all stakeholders on these issues, including HIPAA covered entities; agencies of State, territorial, and tribal governments; law enforcement officials; individuals; and consumer advocates and groups.

III. Public Comments on the ANPRM

Introduction

The Department received over 2,050 comments in response to the ANPRM. Commenters included individuals, State agencies, health care providers, professional organizations, consumer advocacy groups, and other stakeholders.

Individuals generally expressed concern that the NICS, the Federal mental health prohibitor, and the contemplated HIPAA permission, would infringe on their Second Amendment right to bear arms and the right to be afforded due process of law under the U.S. Constitution

Many individual commenters, as well as health care providers, organizations representing providers, and consumer advocacy groups, emphasized the importance of protecting individuals' health information privacy and raised concerns regarding the possible adverse consequences an express permission could have on the patient-provider treatment relationship and individuals' willingness to seek needed mental health care. Other commenters supported the proposal as removing a perceived barrier to an important and necessary public safety measure. Four State agencies and several organizations representing State officials and State-based professional organizations

responded to the specific questions in the ANPRM regarding how NICS reporting occurs in those specific States and their perceptions of HIPAA-related barriers or other challenges related to NICS reporting. We discuss these comments, along with others, in more detail below.

Summary of Comments and Responses

A. Concerns Regarding the NICS and the Federal Mental Health Prohibitor

As noted above, a majority of individual commenters voiced general concern that NICS reporting would lead to infringements on individuals' rights to bear arms and to receive due process of law under the Constitution. Some commenters voiced opposition to any restriction on their right to bear arms.

Many commenters raised concerns with the Federal mental health prohibitor category itself. Some, while supportive of the general proposition that individuals who pose a risk of harm to themselves or others should not have access to firearms, expressed concern that the Federal mental health prohibitor was overly broad and would result in individuals being reported to the NICS Index who do not pose a threat to society. A number of these commenters expressed concern regarding the standard used to determine whether individuals should be reported to the NICS, including those adjudicated as "lack[ing] the mental capacity to contract or manage his own affairs" under 27 CFR 478.11. Several commenters were especially concerned that the prohibitor might include individuals who are adjudicated as temporarily unable to independently manage their Veterans or Supplemental Security Income (SSI) benefits.

Further, many commenters asserted that mental illness is not an effective predictor of gun violence, and that there is no direct correlation between reporting

individuals with mental illnesses to the NICS Index and a reduction in gun violence. Several commenters added that studies have shown that individuals with mental disorders are more likely to be the victims of violent crime by others than the perpetrators. In addition, some commenters specifically objected to individuals that fall within the Federal mental health prohibitor being reported to the NICS on the grounds that the NICS is a “criminal” database.

Many commenters expressed concerns about whether individuals who are subject to the Federal mental health prohibitor receive due process. For example, many individuals were concerned that an individual would be reported to the NICS without a formal adjudication through the judicial system. A few commenters argued that any determination that would subject an individual to the Federal mental health prohibitor should include a review by one or more mental health professionals. In general, commenters urged the Department to allow reporting of only those involuntary commitments that involve due process of law.

State officials and many other commenters emphasized the importance of establishing mechanisms to remove an individual’s name from the NICS when the basis for their inclusion no longer applies. Some of these commenters also expressed concern about the difficulty, including the cost and time involved, of getting an erroneous submission removed from the NICS database. Several commenters noted that individuals whose conditions or circumstances change would not have a process to seek removal from the NICS.

A few commenters suggested that, in addition to the minimum information currently needed to report an individual to the NICS, covered entities should also be

permitted to disclose the date of the disqualifying event. This, they asserted, would make it easier for individuals to determine whether the report was made erroneously.

We acknowledge the concerns of these commenters. However, this proposed rule would not affect the scope of the NICS or the Federal mental health prohibitor. Rather, the rule is intended to address perceptions that HIPAA creates a barrier to entities reporting information to the NICS. More specifically, it would create a way in which covered entities involved in reporting or collecting NICS data may disclose, consistent with the Privacy Rule, the information needed for NICS reporting. It will not expand the categories of prohibited persons or modify other Federal or State laws pertaining to firearms purchases, but would be limited to those covered entities that currently perform the adjudications that make individuals subject to the Federal mental health prohibitor, or that collect information regarding such adjudications on behalf of a State.

Further, the Department clarifies that the proposed HIPAA permission for NICS reporting would be limited to reporting of individuals who are subject to the Federal mental health prohibitor, as defined in Federal law and regulations. DOJ regulations state that this would not include individuals in a mental institution for observation or admitted voluntarily. See 27 CFR 478.11 (Definitions).¹⁹ Thus, individuals who are subject to the Federal mental health prohibitor are afforded the opportunity for judicial review or other due process.

We acknowledge the commenters' concerns with respect to opportunities for remediation and note that individuals who believe they are wrongly denied the purchase

¹⁹ DOJ has proposed clarifications to 27 CFR 478.11. The DOJ proposal is published elsewhere in this issue of the Federal Register. The proposed regulatory text would not alter this aspect of the definition of "committed to a mental institution."

of a firearm can visit <https://forms.fbi.gov/nics-appeals-request-form> to find out more information and appeal their denial. Further, some States have implemented programs providing for relief from disabilities under the Federal mental health prohibitor. Relief from disabilities is a process by which an individual, who would otherwise be prohibited from purchasing a firearm under the Federal mental health prohibitor, may apply to the lawful authority in the State where the commitment or adjudication occurred for relief. The lawful authority must grant relief if it can be established that the circumstances regarding the disability and the applicant's record and reputation are such that the applicant will not be likely to act in a manner dangerous to public safety, and the granting of relief would not be contrary to the public interest. States' processes for granting relief vary.

B. Comments Regarding NICS Reporting Barriers and Creating an Express Permission in the HIPAA Privacy Rule

1. State Processes for Reporting to the NICS

Health agencies from three States responded to the ANPRM's specific questions regarding NICS reporting in those States. An official from the Washington State Department of Social and Health Services explained that a HIPAA covered State agency had been responsible for reporting to the NICS until 2009, when a new State law transferred reporting responsibility to the State's Administrative Office of the Courts. Officials from the Colorado Department of Health Care Policy and Financing and the North Carolina Department of Health and Human Services stated that non-HIPAA covered entities in those States are responsible for reporting to the NICS (the State Bureau of Investigation and the county Clerks of Court, respectively). Three of the State

agency commenters added that entities in their States also do not experience any other, non-HIPAA related, barriers to reporting to the NICS.

2. Creating an Express Permission

Two of the State agency commenters agreed with our statement in the ANPRM that creating an express permission in HIPAA for disclosures to the NICS would resolve any perceived ambiguity and be generally beneficial. Several other commenters agreed, and asserted that an individual's right to the privacy of his or her medical records should not be placed ahead of the safety and welfare of the population as a whole. A few commenters noted that HIPAA was intended to protect the privacy of individuals' health information, not to protect individuals from being identified as potential threats to others.

In addition, the Law Center to Prevent Gun Violence reported that, while a majority of States have enacted laws relating to reporting information to the NICS or a State repository, HIPAA continues to be cited as a perceived barrier to reporting to the NICS in a number of States. This commenter suggested that the perception of a barrier may arise because HIPAA's permission for uses and disclosures that are required by law would not permit HIPAA covered entities to disclose information for NICS purposes in States that have enacted laws authorizing, but not requiring, such reporting. Further complicating disclosures to the NICS, according to this commenter, is the fact that at least eleven States rely, at least in part, on a mental health facility to report information on individuals in a prohibited category. This commenter reported that all of those States have statutes requiring such reporting, but noted that some of the State laws only require reporting to State repositories, and not to the NICS database. Finally, the National Center for State Courts asserted that reporting to the NICS by entities in a State's judicial system

can be challenging due to varying interpretations as to whether or when HIPAA may affect such reporting. This commenter felt an express permission under HIPAA would help resolve this perceived ambiguity.

Some commenters agreed that, if a permission were created, HIPAA's minimum necessary provisions should apply to any disclosures for reporting to the NICS database. These commenters appreciated the Department's assurance that an individual's treatment record, or any other clinical or diagnostic information, is not needed for the NICS, and we would not consider permitting the disclosure of such information under a proposed rule.

In addition, several commenters urged that any HIPAA exception be limited to reporting of "commitments" as defined by 27 CFR 478.11, as these commenters noted, there exists a great variance under State law as to what constitutes a commitment. Several commenters requested clarification on what constitutes a commitment under the Federal mental health prohibitor. One commenter specifically urged the Department to not amend the HIPAA Privacy Rule until the DOJ revises the Gun Control Act regulations to clarify the standards under which an individual becomes subject to a statutory prohibitor.²⁰

A number of commenters argued that the proposed permission was unnecessary, some agreeing with the ANPRM's statement that HIPAA's existing permissions (e.g., for uses and disclosures required by State law) largely permit NICS reporting to take place. However, it should be noted that several commenters expressed, and thus may have based

²⁰ We note that DOJ has proposed clarifications to the relevant regulations defining the categories of persons who are prohibited from possessing firearms. The DOJ proposal is published elsewhere in this issue of the Federal Register.

their comments on, the misconception that the Privacy Rule's permission to disclose for public health purposes, law enforcement purposes, or to prevent a serious and imminent threat, currently allow for disclosures to the NICS. As we noted in the ANPRM, NICS reporting would not be consistent with the conditions the HIPAA Privacy Rule places on such uses and disclosures. See conditions listed at 45 CFR 164.512(b), (f), and (j).

Many commenters believed a change to the Privacy Rule to be unnecessary because the information generally is reported to the NICS by non-HIPAA covered entities. One commenter pointed out that, even in States that allow mental health providers to commit individuals without prior adjudication, in which case a HIPAA covered provider might be the sole possessor of certain information related to the Federal mental health prohibitor, such information eventually must be shared with the court system, usually within a designated timeframe. This commenter and others argued that it would be more appropriate for a court system, rather than providers, to report information for NICS purposes. A few commenters suggested that, where records relevant to the Federal mental health prohibitor are not available to a judicial agency, another State agency or a State's Office of Attorney General should be responsible for reporting.

Some commenters were opposed to the creation of any express permission. Many mental health advocates and individual commenters voiced concern that an express HIPAA permission for reporting to the NICS information relevant to the Federal mental health prohibitor would reinforce and exacerbate the stigma surrounding mental illness. In addition, many commenters expressed concern that creating an express permission to disclose information for NICS purposes would harm the patient-provider relationship and discourage some individuals from seeking needed mental health treatment, due to fear

that their doctor might disclose otherwise confidential communications about particularly sensitive information, such as mental health treatment information. Some commenters expressed particular concern that a change to the Privacy Rule would adversely affect veterans by deterring individuals with post traumatic stress disorder (PTSD) and other mental health issues from seeking mental health services for fear of losing their firearms.

After considering the comments we received, we agree that the creation of an express permission in the HIPAA Privacy Rule to disclose information relevant to the Federal mental health prohibitor for NICS purposes is necessary to address ambiguity and ensure relevant information can be reported for this important public safety purpose. Thus, as discussed more fully below, we propose to permit certain covered entities to disclose limited information for NICS reporting purposes.

It is important to note that a mental health diagnosis does not, in itself, make an individual subject to the Federal mental health prohibitor, which requires an involuntary commitment or adjudication that the individual poses a danger to self or others or lacks the mental capacity to contract or manage their own affairs. For example, with respect to the Federal mental health prohibitor, concerns about veterans being reported to the NICS based solely on a diagnosis of PTSD are misplaced. Still, we acknowledge commenters' concerns about possible detrimental effects of an express NICS disclosure provision on individuals' relationships with their health care providers, or on individuals' willingness to seek care in the first place. We agree that encouraging individuals to obtain appropriate treatment is critical to both individuals' health and the public's safety. Therefore, we have narrowly drawn this proposed permission such that it would not apply to the vast majority of treating health care providers, who do not perform the formal involuntary

commitments or other adjudications that make an individual subject to the Federal mental health prohibitor, and do not serve as repositories of information about such commitments and adjudications. Those health care providers do not report to the NICS currently and this would not change under the proposed rule.

The Department has carefully tailored the proposed permission to generally apply to entities that are not directly involved in treatment to minimize any potential adverse unintended consequences, such as discouraging individuals from seeking mental health treatment due to concerns that their provider might report them to the NICS. Instead, as we explain more fully below in the description of the rule, only those HIPAA covered entities that conduct the involuntary commitments or other adjudications that make an individual subject to the Federal mental health prohibitor, or that serve as repositories of information about such adjudications, would be permitted to rely on the proposed express permission to disclose information for NICS reporting purposes.²¹

The Department is soliciting comment on whether the permission should instead be broad enough to also include reporting of persons to the NICS who are subject to State firearm prohibitions, in light of the many State laws that restrict firearms possession for mental health related reasons. It is possible that extending the permission in this way would expand the number of potential reporting entities to include more covered entities that provide treatment. We describe the potential implications of expanding the scope of the permission to include State law prohibitors more fully below.

²¹ We note that other provisions of the HIPAA Privacy Rule that permit covered entities to disclose information for public policy purposes remain in effect. Thus, where a HIPAA covered entity, including an entity not falling within the proposed provision, is required by law to disclose to the NICS, such disclosures would continue to be permitted under the Privacy Rule.

In addition, the proposed provision would permit those entities to disclose only the minimum necessary information for NICS reporting purposes. NICS does not access or maintain diagnostic or clinical information, so such information would not be considered the minimum necessary. The Department is soliciting comment on whether to permit the disclosure of certain additional identifying information (but not to include diagnostic or clinical information) that would help the NICS make accurate matches or rule out matches based on the additional information. These additional identifiers are discussed below in the description of the proposed rule.

We believe that the proposed change would appropriately protect and preserve individuals' privacy interests, the patient-provider relationship, and the public's health and safety. We emphasize that most covered entities, including treating providers who do not also perform formal involuntary commitments or other adjudications that make an individual subject to the Federal mental health prohibitor, as well as business associates, will not be disclosing information about individuals directly to the NICS under this proposal. We expect most reporting to continue to be done by the judicial system. However, where the judicial system lacks the information needed, or where the judicial system is not the appropriate entity to report individuals to the NICS, this proposal, if finalized, will give States and covered entities additional flexibility to ensure accurate information is reported to the NICS.

C. Other Comments

1. Privacy, Security, and Uses of NICS Information

A few commenters requested information on whether information in the NICS can be accessed by government officials for purposes other than firearm purchase

background checks. In addition, some commenters raised concerns regarding the privacy and security protections afforded to information reported to the NICS, including protections for that information when held by States and while in transit.

The relevant regulations permit NICS background checks in conjunction with the transfer of a firearm, issuance of firearm or explosives permits or licenses, as well as in conjunction with ATF civil or criminal law enforcement investigations relating to the Gun Control Act or National Firearms Act. See 28 CFR 25.6(j).²² The NICS cannot be used for purposes beyond those articulated in the governing regulations, including for general law enforcement activities.

The DOJ regulations make clear that FFLs can initiate NICS background checks only in connection with a firearm transaction requiring a NICS background check. FFLs are prohibited from initiating a query to the NICS for any other purpose. Further, when an individual prohibited from possessing a firearm attempts to obtain a firearm from an FFL, the FFL receives a response indicating only that the transfer has been denied or delayed pending further review, but does not have access to information about the applicable prohibitor or any other additional information regarding the reason for the delay or denial.

With respect to the privacy and security of information reported for NICS purposes, the DOJ has established policies and procedures for ensuring the privacy and security of NICS data in its possession, including physical security and safeguards, such as access restrictions. Further, the DOJ requires State and local law enforcement

²² See Gun Control Act, 18 U.S.C. Chapter 44; National Firearms Act, 26 U.S.C. Chapter 53; see also 28 CFR 25.6(j), 63 FR 58303, 58308-58309.

agencies involved in conducting background checks to observe certain security policies and procedures when processing NICS background checks.

Finally, in response to a question in the ANPRM about the confidentiality of information that has been collected by a repository for NICS reporting, several commenters, including officials from North Carolina, Washington, and Colorado, indicated that the individually identifiable information collected for NICS reporting could not be made publicly available under State public records laws. Further, we note that to the extent a HIPAA covered entity is maintaining and reporting information relevant to the Federal mental health prohibitor that is protected health information (including demographic information), such entities must continue to protect the information in accordance with the HIPAA Privacy and Security Rules, which includes ensuring appropriate safeguards to protect the information as it is maintained and transmitted.

2. Improving the Current Mental Health System and Enforcement of Other Laws

Several commenters recommended better tracking of firearms and better enforcement of existing laws in place of a HIPAA modification. Other commenters urged the Department to focus on improving the current mental health care system in order to reduce gun violence associated with mental illness.

The Department continues to support efforts by the Administration to dispel stigmas relating to mental illness and to encourage individuals to seek voluntary mental health treatment. With the implementation of the Affordable Care Act, millions of Americans who did not previously have coverage will receive coverage for mental health services. Additionally, the Administration has improved access to mental health services for veterans and has supported initiatives to train more mental health professionals and

help educators recognize students showing signs of mental illness and refer them to appropriate services.

3. Application of a HIPAA Permission to Other Prohibitors

Several commenters requested clarification on whether disclosures for NICS reporting under the proposed rule would be limited to the Federal mental health prohibitor or if covered entities could disclose protected health information related to any of the Federal prohibitors under the Gun Control Act. Some other commenters recommended that the Department amend the HIPAA Privacy Rule to expressly permit such reporting with respect to all of the Federal prohibitors. A few commenters also urged the Department to extend any express permission under the HIPAA Privacy Rule for NICS reporting to include prohibitor categories that State laws have enacted, which may extend beyond the Federal prohibitors. Some commenters suggested creating a provision permitting reporting related to other factors they perceive as associated with gun violence, such as domestic violence and substance abuse.

The Department does not propose to expand the proposed permission to apply to information about individuals who are subject to the other prohibitors listed at 18 U.S.C. 922. HIPAA covered entities are unlikely to have information related to the other Federal prohibitors, with the possible exception of the drug use prohibitor, for which we understand criminal records to be the primary source of information for the NICS. We note that, to the extent that individuals' drug use results in their being involuntarily committed, those individuals would be subject to the Federal mental health prohibitor and this proposed permission would apply.

Some States have enacted their own laws prohibiting the possession or receipt of firearms for reasons related to mental health and may prohibit the purchase or possession of a firearm by additional individuals who are not otherwise subject to the Federal mental health prohibitor. For example, some States may temporarily prohibit firearm possession by individuals who have voluntarily committed themselves to inpatient treatment, which currently does not make an individual subject to the Federal mental health prohibitor. As noted above, some States currently collect and report to the NICS the identities of individuals who are subject to State prohibitors, as well as the Federal prohibitors. To the extent that States have enacted their own prohibitions related to mental health, State law may also reduce barriers by requiring reporting to the NICS by those making the mental health assessments that make individuals subject to a State prohibition. However, the Department requests comment on whether HIPAA is perceived as a barrier to reporting to the NICS information about individuals who are subject to State law firearm prohibitions and whether the final rule should address this barrier.

Although the NICS has a role in helping to enforce State firearms prohibitions intended to keep firearms out of the hands of certain individuals for reasons related to mental health, the NICS Index currently does not contain information about all individuals who are subject to such prohibitions. The Department seeks comment on whether the proposed permission should be broadened to include information relevant to those State law prohibitions, as well as information relevant to the Federal mental health prohibitor. Expanding the permission would ensure that relevant State law prohibitor information could be reported to NICS in States that do not otherwise require the reporting. At the same time, however, there are implications to expanding the permission

to encompass State law prohibitors, which may be broader than the Federal mental health prohibitor. For example, if more entities in States with their own prohibitors have the authority to make determinations that subject individuals to a firearms prohibition, there would be an increased likelihood that more treating providers would be permitted to report information to the NICS. In addition, there may be State laws that prohibit the possession or receipt of a firearm by individuals with particular mental health diagnoses or an assessment of “dangerousness” with correspondingly different procedural protections for individuals. The Department is seeking comment on whether these concerns are borne out in any States and whether the proposed permission should be broadened to include information relevant to those State law prohibitions.

4. Notice

A few commenters asked whether individuals would be notified if their provider disclosed their protected health information for NICS reporting purposes. If such notification were not required, commenters recommended that there be a way for individuals to find out that their provider disclosed their information for such purposes. One commenter asked whether covered entities would be required to revise their Notice of Privacy Practices to inform individuals that the entities might make disclosures for NICS reporting purposes.

We are not proposing new notification requirements.²³ Further, the Department would not require covered entities to revise their Notices of Privacy Practices to specifically reference this new provision. Existing notices that more generally refer to

²³ We note that individuals who have tried to purchase a firearm and been denied can appeal to the FBI (and, in some States, to the NICS Point of Contact for the State), and learn the reason for the denial, if they believe they have been erroneously reported.

the types of disclosures each covered entity is permitted to make, including disclosures for the public policy purposes under 45 CFR 164.512, would suffice.

5. HHS Authority

Several commenters argued that any amendment to HIPAA to provide an express permission for reporting to the NICS database should be passed by Congress, not created by HHS. These commenters argued that the Administration would overstep its authority if it adopted a regulatory change that Congress chose not to enact and that this would violate the principle of separation of powers. Additionally, several commenters argued that under the principle of federalism, regulation of firearms should be left to the States.

We note that Congress, when it enacted HIPAA, provided the Department with general authority to determine the permissible uses and disclosures of covered entities and modify the HIPAA standards as appropriate. It is under this authority that the Department has proposed to modify the Privacy Rule to permit certain disclosures for the purpose of NICS reporting.

6. Additional Guidance

Several commenters asked for additional guidance materials, training, and other outreach efforts from the Department to help covered entities, State agency officials, State legislatures, and State judiciaries better understand HIPAA's permitted and required disclosures. Some commenters specifically cited HIPAA as a perceived barrier to State legislatures passing laws requiring NICS reporting due to misconceptions about HIPAA preempting State law, and requested that the Department conduct outreach to explain HIPAA's preemption provisions. Other commenters urged the Department to increase its outreach efforts to encourage individuals to seek voluntary mental health services.

The Department anticipates issuing guidance to both address misconceptions (e.g., such as the perception that HIPAA is a barrier to State legislatures passing laws requiring reporting) and to help covered entities comply with the rule. With respect to the latter, we intend to work with DOJ to issue additional guidance on the categories within the Federal mental health prohibitor,²⁴ variations in State law, and when and how the HIPAA permission would apply. We will continue to evaluate additional areas that may benefit from further guidance.

Finally, the Department will continue its efforts to increase access to, and utilization of, needed mental health care services.

IV. Overview of the Proposed Rule

We are proposing to revise 45 CFR 164.512 of the Privacy Rule by adding a new category of permitted disclosures to 45 CFR 164.512(k), which addresses uses and disclosures for specialized government functions. The new provisions at (k)(7) would permit certain covered entities to disclose the minimum necessary demographic and other information for NICS reporting purposes, which would not include clinical, diagnostic, or other mental health information.

There is a strong public safety need for this information to be accessible to the NICS, and some States are currently under-reporting or not reporting this information at all. From what we understand, and what we have heard from commenters, most of the information relevant to the Federal mental health prohibitor is held by entities that are not covered by HIPAA. For those few HIPAA covered entities that may be involved in the relevant commitments or adjudications, the Privacy Rule contains paths for disclosure,

²⁴ We note that DOJ has proposed clarifications to the regulatory definitions relevant to the Federal mental health prohibitor. The DOJ proposal is published elsewhere in this issue of the Federal Register.

but these do not appear to be sufficient. Therefore, we propose to add another, narrowly tailored, permission for HIPAA covered entities that perform the commitments or adjudications that make individuals subject to the Federal mental health prohibitor, or that act as repositories of NICS records on behalf of a State, to use and disclose certain information for NICS reporting purposes. To the extent that some covered entities may perform adjudicatory or repository functions in States that have not enacted laws requiring reporting to the NICS, and a subset of those may be unable to achieve hybrid entity status for administrative or other reasons, this permission would remove a barrier to their reporting and provide clarity. Importantly, the proposed permission would focus on those entities performing the relevant commitment, adjudicatory or repository functions, not on those performing solely treatment functions.

We note that the proposed modification to the Privacy Rule would merely permit, and not require, covered entities to report to the NICS. In addition, it would not place additional limitations on or otherwise affect the currently existing permitted uses and disclosures of protected health information under the Privacy Rule. Thus, for example, the Rule's current permissions for uses and disclosures required by other law, including State law, would remain unchanged, as would provisions permitting uses and disclosures for law enforcement purposes as part of a specific investigation, or to avert a serious and imminent threat. See 45 CFR 164.512(a), (f), and (j).

V. Description of the Proposed Rule

The following describes the specific provisions of the proposed rule. Those interested in commenting on the proposed rule can assist the Department by preceding discussion of any particular topic with a citation or reference to the aspect of the

proposed rule being discussed. While we request comment on several specific questions, we welcome comments on any aspect of the proposed rule.

General Rule

Paragraph (k)(7) would permit uses and disclosures of protected health information for purposes of reporting to the NICS or a State-designated entity the identities of individuals who are subject to the Federal mental health prohibitor under 18 U.S.C. 922(g)(4), provided the conditions in the remaining paragraphs under (k)(7) are met. We do not intend with this paragraph to require formal designations by the States, but we would expect States to be able to identify the responsible entity. We request comment on whether the proposed language encompasses all entities that are responsible for reporting to, or otherwise collecting information for, the NICS on behalf of the States.

The proposed permission would not permit covered entities to use or disclose the protected health information of individuals who are subject to one or more of the other prohibitors listed at 18 U.S.C. 922(g), as the lack of an express HIPAA permission for reporting information relevant to the Federal mental health prohibitor is a limited problem and we have not heard that there is a similar issue with respect to the other prohibitors. Thus, for example, a covered entity would not be able to use this permission to use or disclose information about an individual who is an unlawful user of or addicted to any controlled substance (18 U.S.C. 922(g)(3)), except to the extent the individual is also subject to the Federal mental health prohibitor. We note that other laws may impact disclosures related to the other prohibitors, including 18 U.S.C. 922(g)(3).

We propose to limit the permission to uses and disclosures about individuals who are subject to the Federal mental health prohibitor. As discussed above, we request

comment on the scope of the permission, specifically with regard to whether the permission should be broadened to allow covered entities to disclose the identities of individuals who are prohibited by Federal or State law from possessing or receiving firearms for reasons related to mental health.

Applicability

Paragraph (k)(7)(i) would apply the express permission only to covered entities that function as repositories of information relevant to the Federal mental health prohibitor on behalf of a State, or that are responsible for ordering the involuntary commitments or other adjudications that make an individual subject to the Federal mental health prohibitor. The Federal prohibitor regulations define an involuntary commitment as a formal commitment of a person to a mental institution by a court, board, commission, or other lawful authority. It does not apply to individuals in a psychiatric facility for observation or who have been admitted voluntarily. The other applicable adjudications include determinations by a court, board, commission, or other lawful authority that persons are a danger to themselves or others, or lack the mental capacity to contract or manage their own affairs, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease. See 27 CFR 478.11 (Definitions).²⁵ This NPRM refers to the involuntary commitments and other applicable adjudications as, collectively, “adjudications that make an individual subject to the Federal mental health prohibitor.”

Our understanding is that lawful authority for performing such adjudications and repository functions rests, for the most part, with entities that operate outside the scope of

²⁵ Note that DOJ has proposed clarifications to this regulation; the DOJ proposal is published elsewhere in this issue of the Federal Register.

HIPAA. However, in the interest of public safety, we want to ensure that relevant adjudications can be reported in the small subset of States in which HIPAA covered entities may make, or collect and report records of, these determinations.

In permitting only entities involved in these adjudicatory or repository/reporting functions to use or disclose Federal mental health prohibitor information for NICS purposes, the proposal would not create a permission for most treating providers to disclose protected health information about their own patients for these purposes. We agree with the commenters who argued that encouraging voluntary treatment is critical to ensuring positive outcomes for individuals' health as well as the public's safety. We also agree with the many commenters who asserted that non-health care entities should and currently do bear primary responsibility for collection and reporting of information relevant to the Federal mental health prohibitor in most States. However, where a HIPAA covered entity is a board, commission, or other lawful authority that makes adjudications that result in individuals being subject to the Federal mental health prohibitor, we believe those entities are most likely to hold records of the relevant adjudications.

We request public comment on the extent to which some States may have vested responsibility for Federal mental health prohibitor reporting in HIPAA covered entities, to what extent records needed for NICS reporting are created or maintained by covered entities, and whether there are circumstances in which health care providers would need to report the identity of an individual subject to the Federal mental health prohibitor to a State designated records repository or directly to the NICS. We also request comment on the types of additional guidance from OCR and/or the NICS that would be helpful for

understanding to which covered entities, and under what circumstances, the proposed permission would apply.

Recipients of Information Disclosures

Paragraph (k)(7)(ii) would provide that a covered entity identified in (k)(7)(i) may use or disclose Federal mental health prohibitor information for NICS purposes either directly to the NICS or to an entity designated by the State as a repository of data for purposes of reporting to the NICS. By clearly delimiting the permitted recipients of such disclosures, the rule would ensure that covered entities do not exceed the intended scope of the permission by disclosing information relevant to the Federal mental health prohibitor to, for example, law enforcement agencies that do not operate as repositories of data for purposes of reporting to the NICS. Again, as stated above, the Privacy Rule's existing permissions to use or disclose protected health information for specific law enforcement investigations, as provided in 45 CFR 164.512(f), would remain unchanged. We request comment on whether there are States in which a type of entity not described in this proposed paragraph is responsible for NICS reporting and needs to be able to receive NICS data from a HIPAA covered entity.

Limitations on the Information Used or Disclosed

Paragraph (k)(7)(iii) would strictly limit the information used or disclosed for NICS reporting purposes to the minimum necessary for such purposes. The Privacy Rule requires uses and disclosures of protected health information to be limited to the minimum necessary for their intended purpose, and in the proposed regulation text, we make clear that only limited demographic and other information would constitute the minimum necessary for NICS reporting. At this time, we would consider the minimum

necessary information to include an individual's name; date of birth; sex; a code or notation indicating that the individual is subject to the Federal mental health prohibitor; a code or notation representing the reporting entity; and a code identifying the agency record supporting the prohibition. The proposed modification would not permit the use or disclosure of clinical or diagnostic information for NICS reporting purposes. We request comment on whether, and in what circumstances, HIPAA covered entities or other entities such as courts currently report to a records repository or directly to the NICS information that is not listed in the proposed paragraph.

We are also considering permitting the disclosure of some or all the following additional data elements, which are optional fields for a NICS Index entry, as part of the minimum necessary for NICS reporting purposes: Social Security number, place of birth, State of residence, height, weight, eye color, hair color, and race. From what we understand, these elements are not included in every NICS record, but often are used to confirm that a prospective firearm recipient matches a record searched by the NICS or to eliminate "false positive" background check results. We request public comment on this issue.

VI. Regulatory Analyses

A. Introduction

We have prepared a regulatory impact statement in compliance with Executive Order 12866 (September 1993, Regulatory Planning and Review), Executive Order 13563 (January 2011, Improving Regulation and Regulatory Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), the Unfunded Mandates

Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104-4), and Executive Order 13132 on Federalism.

1. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 135643 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, public health and safety effects, distributive impacts, and equity). Executive Order 135634 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget.

A regulatory impact analysis must be prepared for all major rules that have economically significant effects (\$100 million or more in any one year) or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities (58 FR 51741). Because the proposed rule does not contain any new requirements for covered entities, we estimate that the rule will be cost neutral. We request comment on our assumptions and information on the nature of any unanticipated costs that covered entities may incur as a result of the rule.

Although we expect the economic impact of the rule, including non-quantifiable costs and savings discussed in the regulatory analysis below, to be less than \$100 million annually, we nevertheless conducted an analysis of the costs of the proposed rule.

2. Entities Subject to the Rule

This proposed rule would apply only to covered entities that are responsible for ordering involuntary commitments or conducting other adjudications that make individuals subject to a Federal prohibition against possessing firearms under 18 U.S.C. 922(g)(4) (the Federal mental health prohibitor), or that are otherwise designated by a State to report the identities of such individuals to the NICS. We do not have sufficient data to determine the number of affected entities, but, based on the information available to us, we believe there would be very few. Our understanding is that, for the most part, formal adjudications and repository functions of this nature are conducted by entities, such as court systems or law enforcement agencies, that are not covered by HIPAA. We welcome public comment on the number of covered entities that might be affected by this rule.

B. Why is this rule needed?

This proposed rule is needed to ensure that, where HIPAA covered entities make adjudications causing individuals to become subject to the Federal mental health prohibitor, or serve as repositories of records of such adjudications on behalf of States, those covered entities can report the identities of those individuals to the NICS. Specific permission under the Privacy Rule for these disclosures is necessary to the extent that some States have not enacted laws requiring reporting to the NICS, but a covered entity in the State is nevertheless responsible for such reporting. Importantly, the proposed rule would permit only a small subset of HIPAA covered entities (i.e., those that perform the relevant mental health adjudications or repository functions) to use or disclose only limited, non-clinical information, for NICS purposes. This narrowly tailored permission

would permit these important uses or disclosures for public safety to occur while maintaining a separation between reporting functions and the mental health treatment a patient might be receiving.

C. Qualitative Analysis of Unquantified Costs

The rule would be cost neutral with respect to HIPAA covered entities. The rule would not require entities that already have a NICS reporting process in place to change their current system and would not create new reporting or recordkeeping requirements for any covered entity. The small number of covered entities that would be newly permitted to report to the NICS or a State repository under the rule could begin reporting and may need to develop policies and procedures to do so. As the Privacy Rule only allows the use or disclosure of information, and does not require it, any resulting burden of reporting and associated procedures is attributable to the Federal statutory mental health prohibitor and the NICS system itself. See 28 CFR Part 25, Subpart A (http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr25_main_02.tpl). We acknowledge that those entities that choose to begin reporting may wish to address this change in their HIPAA policies and procedures, as well as explain their procedures to office staff. However, the rule would not require any changes to existing HIPAA policies and procedures. In addition, with respect to training, the rule would not require workforce training beyond what is already required under the HIPAA Privacy and Security Rules, and we do not expect that such entities that choose to report under the rule would do more than ensure that their office staff have copies of the new policies and procedures. We request

comment on these assumptions and on the number of entities that might begin to report to the NICS for the first time, if any.

To the extent that the rule would permit some covered entities to report to the NICS for the first time, there may be an increase in the number of individuals whose identities are newly included in the NICS and who are denied a firearm transfer as a result. As a result, there may be a concomitant increase in applications for relief from disabilities in states that provide such a relief program. However, any burden to individuals completing and submitting the relief application form is attributed to the procedures established by the State where the commitment or adjudication occurred. The procedures for applying for relief in States that have established mental health relief from disabilities programs pursuant to the NICS Improvement Amendments Act of 2007 vary. We received a number of comments on the ANPRM asserting that creating an express permission in the Privacy Rule for NICS reporting would discourage individuals from seeking needed mental health care. We appreciate these concerns and agree with commenters who asserted that individuals' health and the public's safety are best served by encouraging appropriate treatment. We also recognize that discouraging treatment could increase the burden of untreated mental conditions to individuals, in the form of increased suffering and loss of productivity; to the health care system, when individuals with untreated mental illness need emergency hospitalization, for example; and to the public's safety. However, the majority of these commenters expressed the mistaken belief that the proposed permission would allow or require mental health care providers to report diagnostic or clinical information to the NICS. Many of these commenters also voiced concern that an express permission under HIPAA would potentially increase

burdens on providers. Although one commenter suggested that an express permission under HIPAA would help lessen concerns about provider liability for disclosures related to NICS reporting, many more commenters expressed concern that creating an express permission might lead providers to over report their patients due to a fear of liability for failing to report a patient who later commits an act of gun violence.

As explained above, we have carefully and narrowly tailored the proposed rule to apply only to a small number of covered entities that may be responsible for the adjudications that make an individual subject to the Federal mental health prohibitor, or that serve as repositories of data about such adjudications. As such, the proposed rule generally would maintain a separation between treatment functions and NICS reporting functions. In addition, the rule would not permit the use or disclosure of any diagnostic or clinical information, or any other information about an individual that is not the minimum necessary for NICS reporting purposes. Because of these strict limitations on the permitted uses and disclosures, we believe that individuals would not be dissuaded from seeking needed mental health care services as a result of the proposed rule. We welcome comment on this assumption.

Finally, we recognize the intangible burden to individuals of the stigma associated with mental health conditions. We again emphasize, as we did in the ANPRM, that individuals with treated mental health conditions as a group have not been shown to pose an increased risk of gun violence against others compared with the general population, and are in fact more likely to be victims of violence than other members of the general population. We note further that the Federal mental health prohibitor does not apply to all individuals with mental health conditions, but instead a subset of individuals who have

been involuntarily committed or otherwise adjudicated to be a danger to themselves or others, or unable to manage their own affairs, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease. With this proposed rule, the Department is not adopting or endorsing the idea that individuals with mental health conditions pose a danger to society. Rather, the rule would permit a limited number of HIPAA covered entities to report to the NICS the identities of individuals in a particular subcategory of persons who are currently prohibited by Federal law from possessing firearms. This permission would facilitate the enforcement of prohibitions that were established by the Gun Control Act. Therefore, we do not expect that this proposed rule would exacerbate stigma associated with mental health conditions.

We request comment on this assumption and on any other costs that may be associated with the rule.

D. Qualitative Analysis of Unquantified Benefits

While we believe that there may be benefits to public safety as a result of the rule, we are not able to monetize the value of such benefits.

For example, the rule may result in increased reporting to the NICS of individuals who may pose a risk of gun violence related to a serious mental health condition. To the extent that this rule would permit covered entities to report those individuals' identities for NICS purposes, resulting in denial of firearms to those who are prohibited from possessing firearms under Federal law, the rule would provide a public safety benefit. However, we do not have information about whether, or how many, covered entities would begin to report or increase reporting to the NICS as a result of the rule.

An additional benefit of the rule would be to alleviate the concerns of State lawmakers who, according to a handful of commenters, may be reluctant to pursue legislation requiring entities to report Federal mental health prohibitor information for NICS purposes because of a misconception that the HIPAA Privacy Rule would preempt such requirements. As explained more fully above, the Privacy Rule permits uses and disclosures that are required by law. To the extent that State lawmakers harbor this misconception, this rule would serve both to clarify HIPAA's preemption provisions and provide an avenue for NICS reporting that may obviate a need to enact legislation at the State level.

We welcome comment on any of these issues.

E. Additional Regulatory Analyses

1. Regulatory Flexibility Act

The RFA requires agencies to analyze and consider options for reducing regulatory burden if a rule will impose a significant burden on a substantial number of small entities. The act requires the head of the agency to either certify that the rule would not impose such a burden or perform a regulatory flexibility analysis and consider alternatives to lessen the burden. For the reasons explained more fully above in the summary of costs and benefits, it is not expected that the rule would result in compliance costs for covered entities of any size because the rule would not impose new requirements.

2. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose

mandates would require spending in any one year \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$150 million dollars.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from: (1) Imposing enforceable duties on State, local, or Tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or Tribal governments under entitlement programs. As this proposed rule would not impose enforceable duties or affect entitlement programs, UMRA does not require us to prepare an analysis of the costs and benefits of the rule. Nonetheless, we have done so in accordance with Executive Orders 12866 and 13563, and present this analysis in sections C and D above.

3. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

The Federalism implications of the HIPAA Privacy and Security Rules were assessed as required by Executive Order 13132 and published as part of the preambles to the final rules on December 28, 2000 (65 FR 82462, 82797) and February 20, 2003 (68 FR 8334, 8373), respectively. This proposed rule would not impose requirements, or any associated costs, on State and local governments. Regarding preemption, the preamble to the final Privacy Rule explained that the HIPAA statute dictates the relationship between State law and Privacy Rule requirements. Therefore, the Privacy Rule’s existing preemption provisions do not raise Federalism issues, and these provisions would not be

affected by this proposed rule. In addition, we again emphasize that the proposed modification to the rule would not require covered entities to make disclosures that are prohibited by State law, nor would it prevent disclosures required by State law. For these reasons, the rule would not have Federalism implications.

F. Accounting Statement

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the costs associated with the rule. As explained above in the RIA, we expect that the rule would be cost neutral. However, we invite comment on potential costs associated with the rule, including costs to covered entities that choose to amend written HIPAA policies and procedures or train staff.

VII. Collection of Information Requirements

This proposed rule does not contain new requirements for information collections (i.e., reporting, recordkeeping, and third-party disclosures) under the Paperwork Reduction Act.

List of Subjects in 45 CFR Part 164

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medical research, Medicare, Privacy, Reporting and recordkeeping requirements, and Security.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR Subtitle A, Subchapter C, part 164, as set forth below:

PART 164—SECURITY AND PRIVACY

1. The authority citation for part 164 continues to read as follows:

AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d-1320d-9; sec. 264, Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)); and secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279.

2. Amend § 164.512 by adding paragraph (k)(7) to read as follows:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

* * * * *

(k) * * *

(7) *National Instant Criminal Background Check System.* A covered entity may use or disclose protected health information for purposes of reporting to the National Instant Criminal Background Check System the identity of an individual who is prohibited from possessing a firearm under 18 U.S.C. 922(g)(4), provided the covered entity:

(i) Is a State agency or other entity that is, or contains an entity that is:

(A) An entity designated by the State to report, or which collects information for purposes of reporting, on behalf of the State, to the National Instant Criminal Background Check System; or

(B) A court, board, commission, or other lawful authority that makes the commitment or adjudication that causes an individual to become subject to 18 U.S.C. 922(g)(4).

(ii) Discloses the information to:

(A) The National Instant Criminal Background Check System; or

(B) An entity designated by the State to report, or which collects information for purposes of reporting, on behalf of the State, to the National Instant Criminal Background Check System; and

(iii) (A) Discloses only the limited demographic and certain other information needed for purposes of reporting to the National Instant Criminal Background Check System; and

(B) Does not disclose diagnostic or clinical information for such purposes.

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Dated: December 31, 2013

Kathleen Sebelius,

Secretary.

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