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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: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or “the Department”) is issuing this final rule 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 established under the Gun Control Act of 1968 and implementing regulations issued by the Department of Justice (DOJ) 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 final rule, only covered entities with lawful authority to make the adjudications or commitment decisions that make individuals subject to the Federal mental health prohibitor, or that serve as repositories of information for NICS reporting purposes, are permitted to disclose the information needed for these purposes. The disclosure is restricted to limited demographic and certain other information needed for NICS purposes. The rule specifically prohibits the disclosure of diagnostic or clinical information, from medical records or other sources, and any mental health information beyond the indication that the individual is subject to the Federal mental health prohibitor.

DATES: *Effective date:* This final rule is effective on [OFR insert 30 days after the date of publication in the Federal Register].

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 proposed, and now finalizes, 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 National Instant Criminal Background Check System (NICS)

The Brady Handgun Violence Prevention Act of 1993, Pub. L. 103-159 (Brady Gun Law), 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 rule 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 determined 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,

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 to the institution by a court or other lawful authority. The term does not apply to a person voluntarily admitted to a mental institution or in a mental institution merely for observation.

condition, or disease.^{3,4}

The Brady Gun Law established the NICS to help enforce these prohibitions, as well as State law prohibitions on the possession or receipt of firearms.⁵ 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 who are ineligible to purchase firearms. 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.⁶ 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 (e.g., an order for involuntary commitment). 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 queries the NICS Index and

³ The term used in the statute is “adjudicated as a mental defective. 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.

⁴ This rule refers to the involuntary commitments and other applicable adjudications as, collectively, “adjudications that make an individual subject to the Federal mental health prohibitor.”

⁵ See Pub. L. 103-159, 18 U.S.C. 921-925, and implementing regulations at 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); and 42 U.S.C. 3759(b) (allocating a percentage of certain DOJ funds for State reporting of NICS data).

⁶ 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>. We note also that State law may be more restrictive than Federal law in some cases.

certain other national databases⁷ 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),⁸ 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 4473.⁹

The FFL then 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 does contain prohibiting

⁷ 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>.

⁸ These exceptions are listed in the Bureau of Alcohol, Tobacco, Firearms and Explosives (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.

⁹ 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>.

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.¹⁰ 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.¹¹

Although FFLs are required in most cases to request a background check through the NICS before transferring a firearm to a prospective buyer,¹² Federal law does not require State agencies to report to the NICS the identities of individuals who are prohibited from purchasing firearms under either Federal or State prohibitors, 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 2007, 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 possession.¹³ In

¹⁰ 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.

¹¹ 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.

¹² See 27 CFR 478.102. Exceptions to this requirement are referenced in FN 8 above, and listed in the regulation at 27 CFR 478.102(d).

¹³ 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

addition, some States have 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.

States generally report criminal history information to the other relevant databases that are checked by the NICS; however, many States continue to report little if any information concerning individuals subject to the Federal mental health prohibitor (or the other Federal prohibitors) to the NICS Index.¹⁴ As a result, 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 who are prohibited from possessing or receiving firearms under State law.

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 (PHI) 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 PHI with the individual’s written authorization, or as otherwise expressly permitted or required by the HIPAA Privacy Rule.

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.

¹⁴ Federal law does not require States to submit reports to any of the three databases (the NICS Index, the III, and NCIC) accessed during a NICS Check.

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 PHI 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.¹⁵

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 as a mental defective."¹⁶ 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 determined 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. In many cases, these records are not subject to HIPAA. 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 are a danger to themselves or others, or are incapable of managing their own affairs, occur through a legal process in the court system.

¹⁵ See 45 CFR 164.512.

¹⁶ See 18 U.S.C. 922(g)(4).

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 believe that certain of these lawful authorities or repositories also may be HIPAA covered entities (e.g., a State health agency may be a covered entity).

As we described in the NPRM, 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 two ways in which covered entities can currently report to the NICS (without the individual's authorization). First, a covered entity can disclose the relevant information to the NICS where a State has enacted a law that requires (and does not merely authorize) such reporting.¹⁷ Second, where a State has not enacted such a law, a HIPAA covered entity that performs both health care and non-health care functions (e.g., NICS reporting) could become a hybrid entity under HIPAA so that the Privacy Rule applies only to its health care functions. A covered entity can achieve hybrid entity status by designating its health care components as separate from other components, documenting the designation, and implementing policies and procedures to prevent unauthorized access to PHI by the entity's non-

¹⁷ 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).

covered components.¹⁸ Under these circumstances, the covered entity can report prohibitor information through its non-HIPAA covered NICS reporting unit without restriction under the Privacy Rule. These provisions remain in effect and are not altered by the amendments to the Privacy Rule that we issue today.

However, despite these avenues for disclosure, many States still were not reporting to the NICS essential information on persons prohibited from possessing firearms for reasons related to mental health; concerns were raised that the HIPAA Privacy Rule's restrictions on covered entities' disclosures of PHI might be preventing certain States from reporting the relevant information to the NICS.

In addition, 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.¹⁹ 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."²⁰ 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

¹⁸ See 45 CFR 164.103, 164.105; 67 Fed. Reg. 53182 (8/14/2002).

¹⁹ 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.

²⁰ 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.

reasons related to mental health may experience challenges to reporting related to the HIPAA Privacy Rule.

II. The ANPRM

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 that (a) are responsible for the involuntary commitments or other adjudications that make individuals subject to the Federal mental health prohibitor, or (b) are designated by a State 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 simpler for States to report the identities of such individuals to the NICS.

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 and whether a modification to the Privacy Rule would help address these issues. We also requested comments on any implications of a modification to the Privacy Rule for the mental health community or for the treatment of individuals, and how the Department might address any unintended consequences of such a modification. We received over 2,050 comments in response from individuals, State agencies, health care providers, associations of health care professionals, consumer advocacy groups, and other stakeholders.

A number of commenters supported creating an express permission as a way to remove a potential barrier to an important and necessary public safety measure, which could help keep firearms out of the hands of individuals who should not have them by strengthening the background check system. Many others 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. In addition, 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. These commenters raised concerns regarding the possible adverse consequences an express permission to report certain information could have on the patient-provider treatment relationship and individuals' willingness to seek needed mental health care.²¹

III. Summary of the NPRM

After considering the public comments received on the ANPRM, we published a Notice of Proposed Rulemaking (NPRM) on January 7, 2014,²² proposing to use the Department's broad authority under HIPAA to specify the permitted uses and disclosures of PHI by HIPAA covered entities. The NPRM proposed 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 NPRM proposed new provisions at (k)(7) that would permit certain covered entities

²¹ Please see the ANPRM for a more thorough discussion of public comments and responses. 78 FR 23872 (April 23, 2013).

²² See 79 Fed. Reg. 784 (January 7, 2014).

to disclose the limited demographic and certain other information needed for NICS reporting purposes.

We indicated in the NPRM that there is a strong public safety need for this information to be accessible to the NICS and that some States are currently under-reporting or not reporting this information at all. Further, although 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's existing paths for disclosure did not appear to be sufficient. We explained that, to the extent that some covered entities perform adjudicatory or repository functions in States that have not enacted laws requiring reporting to the NICS, and that a subset of those may be unable to achieve hybrid entity status due to administrative challenges or other reasons, an express permission would provide clarity and remove a barrier to their reporting.

However, to address concerns regarding an express permission's potential to harm the patient-provider relationship or deterring individuals from seeking needed mental health care, we proposed to narrowly tailor the permission to report information on individuals subject to the Federal mental health prohibitor in a number of ways. Specifically, we proposed to limit: (1) which covered entities could use or disclose PHI for NICS reporting purposes, (2) to whom the PHI could be disclosed, and (3) the scope of the information that could be used or disclosed.

First, the NPRM proposed a new paragraph at 164.512(k)(7)(i) to permit certain NICS disclosures only by those 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. 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.²³ The prohibitor does not apply to individuals in a psychiatric facility for observation or who have been admitted voluntarily; thus, the proposed rule would not have permitted disclosures with respect to those individuals.

With respect to repositories of Federal mental health prohibitor information, we explained further that we did not intend to require States to formally designate the entities responsible for NICS reporting, but that we would expect States to be able to identify the relevant entities.

We noted in the NPRM that our understanding was that lawful authority for performing such adjudications and repository functions rests, for the most part, with entities that operate outside the scope of HIPAA. However, in the interest of public safety, we wanted to ensure that relevant adjudications could be reported in the subset of States in which HIPAA covered entities may make, or collect and report records of, these determinations.

²³ See 27 CFR 478.11 (Definitions).

We explained further that, 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 PHI about their own patients for these purposes. We agreed with the commenters on the ANPRM who argued that encouraging voluntary treatment is critical to ensuring positive outcomes for individuals' health as well as the public's safety, and explained that the NPRM was designed to balance that goal and the public safety interests served by the NICS. We also agreed that non-health care entities 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 involuntary commitments or other adjudications that result in individuals being subject to the Federal mental health prohibitor, we believed those entities too were likely to hold records of the relevant commitments and adjudications.

We requested 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 requested 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.

Second, we proposed a new paragraph at (k)(7)(ii) providing that a covered entity identified in (k)(7)(i) may use or disclose Federal mental health prohibitor information for NICS purposes only 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, we explained that 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.²⁴ We requested comment on whether there are States in which a type of entity not described in this proposed paragraph is responsible for NICS reporting and thus, should be able to receive NICS data from a HIPAA covered entity.

Third, we proposed a new paragraph at (k)(7)(iii) to limit the information permitted to be used or disclosed to what is needed for purposes of reporting to the NICS. This is consistent with the Privacy Rule provision that generally requires covered entities to make reasonable efforts to limit the PHI used or disclosed to the minimum necessary to accomplish the intended purpose. Specifically, in the proposed regulation text, we made clear that only the limited demographic and certain other information needed for purposes of reporting to the NICS could be reported under the permission. We indicated that, at the time, we believed that the necessary information would be the data elements needed to create a NICS Index record: (1) name of the individual; (2) date of birth; (3) sex; (4) a code or notation indicating that the individual is subject to the Federal mental health prohibitor; (5) a code or notation representing the reporting entity; and (6) a code

²⁴ We did not propose to change the Privacy Rule's existing permissions to use or disclose PHI for specific law enforcement investigations, as provided in 45 CFR 164.512(f).

identifying the agency record supporting the prohibition. The proposed regulation text expressly provided that the proposed modification would not permit the use or disclosure of clinical or diagnostic information for NICS reporting purposes. We requested 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 was not listed in the proposed paragraph.

In addition, we explained that we were also considering permitting the disclosure of some or all the following additional data elements, which are optional fields for a NICS Index entry, for NICS reporting purposes: Social Security number, place of birth, State of residence, height, weight, eye color, hair color, and race. As we noted in the NPRM, 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 requested public comment on this issue.

We also proposed to limit the permission to uses and disclosures about individuals who are subject to the Federal mental health prohibitor and not to apply it to disclosures about individuals subject only to State mental health prohibitors. However, we requested comment on this aspect of the scope of the permission, specifically with regard to whether the permission should be broadened to allow covered entities to also disclose the identities of individuals who are prohibited by State law from possessing or receiving firearms for reasons related to mental health.

Finally, we also explained that the proposed permission would apply only with respect to the PHI of individuals subject to the Federal mental health prohibitor and not to

the PHI of those persons who may be subject to the other Federal prohibitors listed at 18 U.S.C. 922(g). The lack of an express HIPAA permission for reporting information relevant to the Federal mental health prohibitor was a limited problem and we had not heard that there was a similar issue with respect to the other prohibitors. Thus, for example, a covered entity would not be able to use the proposed 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 was also subject to the Federal mental health prohibitor. We also noted that other laws could impact disclosures related to the other Federal prohibitors, including 18 U.S.C. 922(g)(3).²⁵

IV. Provisions of the Final Regulation

This final rule adopts the modifications to the HIPAA Privacy Rule as proposed. After considering the comments we received, we continue to believe that the creation of a limited express permission in the HIPAA Privacy Rule to use or disclose certain information relevant to the Federal mental health prohibitor for NICS purposes is necessary to address barriers related to HIPAA and to ensure that relevant information can be reported for this important public safety purpose. Furthermore, this narrowly tailored rule appropriately balances public safety goals with important patient privacy interests to ensure that individuals are not discouraged from seeking voluntary treatment.

Under this final rule, covered entities that order involuntary commitments or make other adjudications that subject individuals to the Federal mental health prohibitor,

²⁵ The ability of certain entities to report individuals who are subject to the Federal prohibitor at 18 U.S.C. 922(g)(3) may be affected by the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2, administered by the Substance Abuse and Mental Health Services Administration (SAMHSA).

or that serve as repositories of the relevant data, are permitted to use or disclose the information needed for NICS reporting of such individuals either directly to the NICS or to a State repository of NICS data. Thus, if a covered health care entity also has a role in the relevant mental health adjudications or serves as a State data repository, it now may disclose the relevant information for NICS reporting purposes under this new permission even if it is not designated as a HIPAA hybrid entity or required by State law to report. This final rule does not create an express permission for covered entities to disclose for NICS reporting purposes the PHI of individuals who are subject to State-only mental health prohibitors.

The Department's rationale for adopting the provisions in this final rule, along with further clarifications and interpretations of the provisions, is explained below in the responses to the public comments on the NPRM.

V. Analysis of and Responses to Public Comments

We received more than 430 public comments in response to the NPRM, including from advocacy organizations, associations of health care and mental health professionals, a state mental health agency, and individual members of the public. A summary of the comments we received on the proposed rule and our responses follow.

A. Comments Regarding Creating an Express Permission for NICS Reporting in the HIPAA Privacy Rule

Comments: A number of commenters expressed general support for including an express permission in the HIPAA Privacy Rule for reporting certain information to the NICS, stating that the rule change would help increase the reporting of information to the NICS, reduce the ability of individuals with serious mental health problems to obtain

firearms, and ultimately lessen the risk of harm to the individuals themselves, law enforcement, and the public.

Several advocacy organizations involved in gun violence prevention agreed with our statements in the NPRM that the HIPAA Privacy Rule and, in some cases, perceptions of the Privacy Rule, may create a barrier to certain entities reporting to the NICS, and that the proposed modification would address this problem. For example, the comment submitted by Mayors Against Illegal Guns (MAIG) indicated that mental health treatment facilities in seven States currently are required by State law to report Federal mental health prohibitor information either directly to the NICS or to State agencies that report to the NICS, which indicates that mental health facilities do in some cases hold the relevant records. MAIG inferred from this information that there likely are other States in which HIPAA covered entities have information that should be reported to the NICS, but that the entities may not be reporting due to concerns about the HIPAA Privacy Rule's restrictions on disclosures. MAIG also cited statements from interviews its researchers conducted with State officials about issues related to NICS reporting and noted that officials from nine States and the District of Columbia had expressed concern that HIPAA, or other privacy requirements, generally prohibited sending records to the NICS, and thus that reporting would violate such requirements. MAIG asserted that whether these cited concerns were based on real or perceived barriers, its research indicated that making clear the ability to report without violating privacy laws tended to

greatly improve state reporting rates, and that the proposed modifications to the Privacy Rule similarly would help states improve their record submissions.²⁶

A number of commenters asserted that increasing reporting to the NICS could, in turn, help to decrease rates of gun violence. One of these commenters cited research indicating that, in one State, having a mental health adjudication record in the NICS database appeared to reduce the chance of a person committing a first violent crime.²⁷

In addition, a number of commenters, including the American Medical Association (AMA), and the American Psychiatric Association (APA), expressed appreciation that the proposed rule would appropriately balance protecting public safety and preserving the patient-physician relationship by narrowly defining the scope of the permission. The AMA stated that its view on the issue of reporting patient information to the NICS is governed by the association's Code of Medical Ethics and policies adopted by the AMA's policy making body. The AMA indicated that the Code of Ethics supports strong protections for patient privacy and, in most cases, requires physicians to keep patient medical records strictly confidential. If there must be a breach in confidentiality, such as for public health or safety reasons, the disclosures must be as narrow in scope as possible. In light of these considerations, the AMA expressed support for the Department's approach.

²⁶ MAIG, *Fatal Gaps, How Missing Records in the Federal Background Check System Put Guns in the Hands of Killers* (Nov. 2011).

²⁷ The commenter cited Jeffrey Swanson, *Preventing Gun Violence Involving People with Serious Mental Illness* in REDUCING GUN VIOLENCE IN AMERICA, INFORMING POLICY WITH EVIDENCE AND ANALYSIS (eds. Daniel W. Webster and Jon S. Vernick, 2013). The study authors note that, "[c]onsidering separately the subgroup of people with serious mental illness who do not have criminal records, our data seem to suggest that the Brady Law background checks can have some positive effect, if enforced. In those with a gun-disqualifying mental health record, risk of violent criminal offending declined significantly after Connecticut began reporting gun-disqualifying mental health records to the NICS." The authors also describe the limitations of the study and add, "[t]hese findings do not prove a causal relationship between the background check system and reduced violent crime."

In contrast, many commenters did not support adding an express permission in the HIPAA Privacy Rule for reporting certain information about persons subject to the Federal mental health prohibitor for NICS purposes. Several commenters asserted that there are only “perceived barriers” related to HIPAA, not real ones, so changing HIPAA would be unlikely to increase the reporting of mental health prohibitor information for NICS purposes. One commenter suggested that, rather than facing obstacles to reporting, States may be choosing not to report on certain categories of prohibited individuals for reasons unrelated to HIPAA – for example, because the States do not believe the individuals pose a danger.

Other comments, some of which highlighted the importance of early and appropriate mental health intervention as the most effective way to prevent violence related to mental illness, expressed concern that the proposed permission would discourage individuals from seeking needed treatment. For example, the National Association of Psychiatric Health Systems (NAPHS) predicted that the public perception of the proposed rule would be that, if an individual disclosed information to a therapist, the therapist would be required to “report” the patient. This commenter argued that, as a result, the proposed rule would create a chilling effect on individuals’ willingness to discuss issues in treatment that could lead to positive resolution rather than violence directed toward themselves or others. A number of commenters also expressed concern that the proposed rule would unfairly target persons with mental illness and perpetuate unfounded and damaging stereotypes about persons with mental illness by sending a message to the public that the Department perceives mental illness as inextricably linked with violence.

Some commenters expressed general concern regarding the effects of the proposed rule on individuals' privacy interests. A number of these commenters argued that communications between patients and their health care providers should be kept confidential under all circumstances.

Response: After considering the comments, we continue to believe that the creation of a limited express permission in the HIPAA Privacy Rule to disclose information relevant to the Federal mental prohibitor for NICS purposes is necessary to address barriers to reporting. In particular, to the extent that some States do not require reporting by law, and reporting entities in those States may face administrative or other challenges in creating a hybrid entity, the HIPAA Privacy Rule may create impediments to reporting that cannot be cured through mere guidance. Therefore, we believe such an express permission will serve an important public safety interest by removing a barrier to reporting that may exist in certain circumstances and thereby potentially increase reporting by States that historically have reported little or no Federal mental health prohibitor data to the NICS due to concerns about violating the Privacy Rule.

Further, we believe that the limitations contained in the narrowly tailored express permission we adopt appropriately respond to commenters' important concerns about discouraging individuals who need mental health treatment from seeking care. First, we limit the permission to only those covered entities that order the involuntary commitments or make the other adjudications that cause individuals to be subject to the Federal mental health prohibitor, or that serve as repositories of such information for NICS reporting purposes. Thus, the rule does not affect most treating providers or create a permission for them to disclose PHI about their own patients for these purposes.

Second, we permit such entities to disclose NICS data only to designated repositories or the NICS. Third, we limit the information that may be disclosed to certain demographic or other information that is necessary for NICS reporting. Finally, we do not expand the permission to encompass State law prohibitor information. These aspects of the provision are discussed more fully below. By limiting the permission in these ways, we protect the patient-provider relationship. Further, we believe these limitations carefully balance an individual's privacy interests with the public safety interest in reporting certain information to the NICS.

In response to concerns that the rule unfairly singles out individuals with mental illness, we emphasize, as we did in the proposed rule, 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 his or her own affairs.

In addition, the Department continues to support efforts by the Administration to dispel negative attitudes and misperceptions 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.

B. Comments Regarding the Scope of the Permission

Expanding to State Law Prohibitors

Comments: We received several comments in response to our question about whether the permission should be expanded to include State law prohibitors. Of these, a minority of commenters supported expanding the proposed rule to permit disclosures of

information about individuals who are subject to State-only mental health prohibitors (i.e., State prohibitors that have different criteria than the Federal mental health prohibitor). Several commenters who advocated for the disclosure of such information for NICS reporting purposes asserted that State law prohibitors would be effective only if accurate and adequate information were submitted to the NICS. One of these commenters argued that State efforts to report disqualifying records to the NICS should be encouraged, not curtailed by confusion over the applicability of the HIPAA Privacy Rules. The commenter also argued that it would create greater confusion not to include the same express permission with respect to State mental health prohibitor information as was proposed for the reporting of information related to the Federal mental health prohibitor.

Another commenter who supported a permission to disclose information about individuals who are subject to State-only mental health prohibitors argued that increasing the disclosures to the NICS about individuals who are prohibited by State law (but perhaps not Federal law) from purchasing firearms could address the situation in which a person who is subject to a prohibitor in the person's State of residence enters another State temporarily for the sole purpose of obtaining a firearm and then returns to the State where ownership is prohibited with a firearm. This commenter voiced the concern that, if the State of residence does not provide information about individuals who are subject to State law prohibitors to the Federal background check system, a FFL in another State would not know that the individual is subject to a prohibitor.

Several commenters asserted that an express permission to disclose information about individuals who are subject to State mental health prohibitors would help to avoid a

misinterpretation that HIPAA prohibits disclosures of PHI relevant to State mental health prohibitors in circumstances when HIPAA otherwise would not. Another commenter argued that, as some State law prohibitors were enacted before HIPAA, State legislators would not have foreseen HIPAA-related obstacles to disclosure or the resulting need to require reporting to the NICS by law; as a result, those States may not have laws in place to require the reporting of State law prohibitors.

One commenter who supported extending the permission argued that the reporting of State mental health prohibitors would be consistent with congressional intent, as expressed through statutes aimed at preventing gun violence. The commenter asserted that the NICS was established under the Brady Gun Law to serve as a central aggregated database of information regarding the identities of individuals who are prohibited from possessing firearms under any Federal, State, or local law.

In contrast, a number of commenters, including several associations of mental health professionals, expressed concern that expanding the reporting permission to apply to State law mental health prohibitors would involve more treating health care providers in NICS reporting, and that individuals would not seek treatment for mental health problems if they felt that simply by seeking treatment they could be reported to the NICS.

Several commenters, including two mental health professional associations, expressed concern that State mental health prohibitors are being expanded in an overly broad manner that will further negative attitudes and misperceptions about mental illness. The commenters pointed to an example of a State statute that requires health care providers to report to the NICS the identities of all individuals with intellectual

disabilities, as well as individuals who voluntarily commit themselves to a mental institution.

The CCDRTF provided additional examples of State law mental health prohibitors that are significantly broader than the Federal mental health prohibitor and expressed concern that many of these State prohibitors apply to individuals without the benefit of an adjudication by a court, board, commission or other lawful authority, as provided for under the Federal prohibitor.²⁸ This commenter asserted that the Federal mental health prohibitor forbids the reporting of information to the NICS about individuals who are subject to broader State mental health prohibitors due to a lack of equivalent procedural protections for such individuals; therefore, this commenter argued, to permit reporting related to State mental health prohibitors would violate the Supremacy Clause and raise due process concerns.

A number of commenters who opposed the reporting of State mental health prohibitors expressed concern that the broadest State law prohibitors would become the de facto national standard if the NICS were to include State law prohibitors. Others raised concerns about the increased complexity involved in accurately maintaining the NICS

²⁸ This commenter described laws enacted in four States. According to the commenter, New York law requires all mental health professionals to report any person undergoing treatment that is “likely to engage in conduct that would result in serious harm to self or others” (citing N.Y. Mental Hygiene Law § 9.46), while New York’s SAFE Act requires mental health treatment providers to report covered individuals to a state database without an adjudicatory process (citing N.Y. Mental Hygiene Law § 9.46). In California, the commenter stated, prohibitors apply to individuals undergoing voluntary inpatient treatment (citing 30 Cal. Welf. & Inst. Code § 8100(a)); and apply to individuals involuntarily held as inpatients under 72-hour holds (citing Cal. Welf. & Inst. Code § 8103(f) and Cal. Welf. & Inst. Code § 5150) without the types of adjudications contemplated under the Federal mental health prohibitor (citing 18 U.S.C. § 922(g); *U.S. v. Rehlander*, 666 F.3d 45, 50 (1st Cir. 2012)). Finally, the commenter noted that Illinois and Hawaii have prohibitors that apply to all individuals who have received particular diagnoses (citing 31 430 Ill. Comp. Stat. 65/8(g) (intellectual disability) and (s) (developmental disability); Haw. Rev. Stat. Ann. § 134-7(c) (persons with significant DSM diagnosed disorder)).

database with the addition of State law prohibitor records, including challenges associated with avoiding or identifying duplicate reports, resulting in less reliability, increased inaccuracy, and improper denial of rights, as well as adding complexity to appeals.

Response: We share the concerns of commenters that, due to the breadth of some State law prohibitors, the inclusion of State-only prohibitors in the permission would increase the involvement of treating providers in NICS reporting, which could negatively affect patient-provider treatment relationships and discourage some individuals from seeking care. While we note that the NICS currently receives some information on State law prohibitors, given these concerns and the importance of protecting the patient-provider relationship, we do not think it is appropriate to expand the permission with respect to HIPAA covered entities. We agree with the commenters who stated that the health and safety of individuals and the public is best served if persons with mental illness obtain appropriate treatment; by limiting the permission to the narrower Federal mental health prohibitor, and carefully tailoring the permission in the ways described throughout this preamble, this final rule is designed to ensure that such persons are not discouraged from seeking care.

With respect to some commenters' concerns about State mental health prohibitors being ineffective without a HIPAA disclosure permission, we note that the Privacy Rule does not affect the reporting of State law prohibitors by non-HIPAA covered entities, which are the entities that maintain most of the relevant information. Moreover, to the extent that covered entities maintain relevant State law prohibitor information and a State wants to ensure that the reporting of this information can occur, the Privacy Rule

provides certain other avenues for disclosure, as we have described elsewhere. For example, although our balancing of interests limits this express permission under HIPAA to disclosures related to the Federal mental health prohibitor, this rule does not prevent State legislators from differently balancing the privacy, health, and public safety issues involved with respect to their State level mental health prohibitors—nor does the Federal mental health prohibitor itself prohibit reporting to the NICS of State law prohibitor information, as a commenter asserted. If State legislators determine that information related to a State-only prohibitor should be disclosed despite any potential chilling effect on seeking treatment, they can enact a State law requiring the relevant entities to report such information. Alternatively, the relevant covered entities can create a hybrid entity, separating their HIPAA covered health care functions from their NICS reporting or repository functions, such that the information maintained by the covered health care component is subject to the Privacy Rule, while information held by the non-covered component can be reported without regard to the Privacy Rule.

We disagree with the commenters who argued that excluding State-only mental health prohibitor information from the permission will create confusion. We do not think this will occur because this final rule clearly indicates that it applies where firearm possession is prohibited under a specific provision in Federal law. We also note that the rule delineates the types of covered entities that are permitted to disclose, the information they are permitted to share, the categories of individuals covered by the permission, and the entities to which they can make such disclosures. In addition, we intend to work with DOJ to develop additional guidance on the categories within the Federal mental health prohibitor. Moreover, we do not believe this final rule will create a misperception that

HIPAA always prohibits the reporting to the NICS of individuals who are subject to State-only mental health prohibitors. As explained elsewhere in this preamble, the Privacy Rule already permits uses and disclosures of PHI that are required by law, including State law reporting requirements; also, HIPAA covered entities that perform both health care and non-health care functions (e.g., NICS reporting) are permitted to create hybrid entities under HIPAA so that the Privacy Rule applies only to their health care functions. This final rule does not change those provisions.

Finally, we do not agree that Congress intended for State (or local) law prohibitor information to be reported to the NICS in all circumstances, such as where doing so would conflict with countervailing privacy concerns due to the treatment relationship between patients and health care providers. Therefore, this final rule balances a variety of important interests, including protecting the privacy of individuals' personal health information, ensuring access to needed mental health care services, and advancing the public safety interests in ensuring that persons who are prohibited by Federal law from purchasing or possessing a firearm for mental health reasons do not gain access to firearms.

Entities Permitted to Report

Comment: Several commenters, including the AMA and the National Association of Psychiatric Health Systems, expressed support for the proposal to limit the permission to only those entities in a State that are directly involved in the relevant adjudications or maintain records of them for NICS reporting purposes. These commenters expressed appreciation for the narrow drafting of the NPRM based on the need to support provider-

patient relationships and encourage individuals with mental illness to seek appropriate care.

However, several advocacy organizations and many individuals argued that direct treatment providers should not be permitted to report information about their patients to the NICS under any circumstances (i.e., even if they are, or are part of, the entity that orders involuntary commitments or conducts other relevant adjudications, or serves as a repository of NICS data). Some of these commenters argued that reports to the NICS database should come only from the judiciary.

Finally, we did not receive responses to the question we posed in the NPRM about whether additional types of covered entities within a State (other than those identified in the proposed regulatory text) might be expected, and thus should be permitted under the Privacy Rule, to report data to the NICS or to a State repository.

Response: We agree with the commenters who emphasized the need to protect the provider-patient relationship, and this final rule addresses such concerns by limiting the permission to those covered entities that also perform an adjudicatory or data repository function. Furthermore, as described more fully elsewhere in this preamble, the permission does not extend to broader State law prohibitors, which may not require a formal adjudication or involuntary commitment and whose inclusion likely would involve more treatment providers in NICS reporting.

In response to comments arguing that only entities in the court system should be permitted to report to NICS, it is our understanding, based on public comments and our fact finding, that courts do not create or maintain records of all of the involuntary commitments or other adjudications that make individuals subject to the Federal mental

health prohibitor. Therefore, for the NICS database to include reports of all persons subject to the mental health prohibitor, it is necessary for certain other entities that create or maintain such information to be able to report. We believe this permission will help strengthen the background check system to ensure that individuals who are prohibited from purchasing or possessing firearms are prevented from obtaining them. We also acknowledge the concerns of commenters who argued that providers should not be permitted to report information about their patients under any circumstances. As explained in more detail elsewhere in this preamble, to address these and other concerns, we have carefully tailored this final rule to limit the involvement health care providers, and to prevent disclosures of diagnostic or clinical information for NICS reporting purposes.

Demographic and Certain Other Information Permitted to Be Reported

Comment: Many commenters specifically voiced support for the NPRM’s proposal not to permit the disclosure of diagnostic or clinical information for NICS reporting purposes. (We also noted in the NPRM that the NICS does not request or contain such information.) For example, the American Medical Association stated that it strongly supported restricting the information disclosed to the limited demographic and other information needed for reporting, as the NPRM proposed. To support the point that NICS reporting is sufficiently limited, another commenter pointed out that the information that is reported to the NICS generally is provided by the individual to a FFL on the required application for the firearm.

In contrast, one commenter asserted that, as written, the proposed permission would grant discretion to state entities to determine the scope of “demographic and

certain other information” to be reported and argued further that DOJ (specifically ATF), not HHS, has authority to define the “minimum” information required by NICS.

In response to our request for comment on whether, and in what circumstances, entities currently report, or should be permitted to report, additional data elements needed to confirm an individual’s identity, the Connecticut Department of Mental Health and Addiction Services (DMHAS) asserted that certain additional data elements are helpful in confirming whether an individual is appropriately excluded from gun purchase or possession in cases where multiple individuals share the same name and date of birth. Several other commenters agreed that permitting the disclosure of additional data elements for NICS reporting purposes would allow more accurate verification of an individual’s identity, resulting in fewer erroneous denials, and would facilitate the correction and updating of NICS entries.

The Connecticut DMHAS and others suggested the inclusion of some or all of the following specific data elements: Social Security number, place of birth, state of residence, height, weight, eye color, hair color, and race. Social Security number and race were cited as the most reliable indicators of an individual’s true identity.

Response: We agree with the commenters who stated that limiting the permission to exclude diagnostic and clinical information appropriately balances individuals’ privacy interests and public safety priorities. We also agree that there may be data elements beyond those needed to create the NICS record (i.e., the individual’s name, sex, and date of birth; as well as codes identifying (1) the Federal mental health prohibitor, (2) the record documenting the involuntary commitment or adjudication, and (3) the entity from which the record initiated) that may be helpful in verifying identity and excluding false

matches. Given that, the final rule provides some flexibility for States or reporting entities. We do not specify in the regulatory text which data elements may be disclosed, but clarify in this preamble that what generally would be considered the information “needed for purposes of reporting to the [NICS]” in § 164.512(k)(7)(iii)(A) would be the data elements required to create a NICS record, as well as the following elements to the extent necessary to exclude false matches: Social Security number, State of residence, height, weight, place of birth, eye color, hair color, and race (and we note that the Federal Bureau of Investigations (FBI) and not ATF has the authority to define the information required by NICS). As indicated above, these are the same elements that were identified in the NPRM.

C. Comments Regarding the NICS and the Federal Mental Health Prohibitor

Comment: Many commenters raised concerns about infringement of individuals’ Second Amendment right to bear arms without due process. A number of these commenters specifically expressed concern that an individual could be reported to the NICS without a formal adjudication through the court system and argued that due process under the Constitution would require a hearing in a court of law before an individual could be made subject to the Federal mental health prohibitor.

Response: We acknowledge the views of the commenters. However, as we explained in the NPRM, these concerns relate to the Federal mental health prohibitor rather than the HIPAA Privacy Rule or this final rule, and thus are outside the scope of this rule. This final rule addresses HIPAA-related barriers to entities reporting certain information to the NICS about individuals who are subject to the Federal mental health prohibitor. The rule does not expand the categories of federally prohibited persons or

modify the criteria for determining that a person is subject to the Federal mental health prohibitor.

Comment: Several disability rights advocates and others asserted that the rule would not result in a decrease in gun violence because mental illness alone does not make a person more likely to commit violence against others. The Consortium for Citizens with Disabilities Rights Task Force (CCDRTF) cited studies indicating that mental illness alone is not statistically related to future violence and that even severe mental illness without drug use or a history of violence is not linked with future violence.²⁹ Several commenters also noted that persons with mental illness are more likely to be the victims of violence than its perpetrators. Alternatively, several commenters argued that, even if there were a link between mental illness and gun violence, the proposed rule is not needed because mechanisms already are in place in place to prevent harm from patients who are a threat to themselves or the public.

Response: We acknowledge the views of the commenters. However, these commenters address the applicability of the Federal mental health prohibitor itself. This final rule does not expand the existing categories of persons prohibited from owning a firearm or modify other Federal or State laws pertaining to firearms purchases. Therefore, these comments are beyond the scope of this rule.

²⁹ CCDRTF cited Eric B. Elbogen & Sally C. Johnson, *The Intricate Link Between Violence and Mental Disorder: Results from the National Epidemiologic Survey on Alcohol and Related Conditions*, 66 ARCH. GEN. PSYCHIATRY 152, 157 (Feb. 2009); David J. Vinkers, *et al.*, *Proportion of Crimes Attributable to Mental Disorders in the Netherlands Population*, 11 WORLD PSYCHIATRY 134 (June 2012). CCDRTF also indicated that other studies showed a modest relationship between serious mental illness and violence, but that other factors (*e.g.*, substance abuse, age, gender and lower economic status) contribute more to increasing the likelihood of committing violence than mental illness alone. They cited R. Van Dorn, *et al.*, *Mental Disorder and Violence: Is There a Relationship Beyond Substance Use?*, 47 SOCIAL PSYCHIATRY AND PSYCHIATRIC EPIDEMIOLOGY 487, 499 (2012).

Comment: Several commenters raised questions about individuals' ability to correct erroneous NICS reports or to have their rights restored when they no longer pose a danger to themselves or others. A number of commenters recommended assuring that the appeals process is free of delay, inexpensive, and easy for individuals to initiate.

Other commenters asserted that the expense to remove oneself from the NICS database is prohibitive for some individuals. As a result, the commenters said, individuals effectively become subject to a lifelong restriction on their Second Amendment right to bear arms, even after they recover from the condition that led to their adjudication and are eligible to apply for relief from disabilities under the Federal mental health prohibitor. Similarly, one commenter argued that, once an individual is reported to the NICS, the "relief from disabilities" process³⁰ is inadequate for remediation due to a lack of Federal funding to support State programs, and wide variability in State programs to provide relief as a result. Another commenter recommended allocating additional funding to support State "relief from disabilities" programs.

Response: These comments are outside the scope of the rule. However, we acknowledge the commenters' concerns with respect to opportunities for remediation and note that individuals who believe they are wrongly denied the purchase of a firearm can visit <https://forms.fbi.gov/nice-appeals-request-form> to find out more information and appeal their denial. In addition, the NICS Improvement Amendments Act of 2007 authorized grants for States that implement programs for "relief from disabilities" in accordance with the Act.³¹ These programs are required to establish processes by which

³⁰ See footnote 13 above.

³¹ The DOJ Bureau of Justice Statistics provides state data on NICS Act Record Improvement Program (NARIP) Awards (*available at* <http://www.bjs.gov/index.cfm?ty=tp&tid=491#promising>).

an individual who is subject to the Federal mental health prohibitor may apply for relief to the State where the relevant commitment or adjudication occurred. While States' processes for granting relief vary, the Act requires that relief be granted 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.³²

Comment: A number of commenters expressed concern that a finding of mental incompetence by the Veterans Administration (VA), which could make an individual subject to the Federal mental health prohibitor and cause the individual to be reported to the NICS, may be based solely on a determination that the veteran is unable to handle financial affairs, without regard to dangerousness. The commenters argued that these veterans do not receive due process before being made subject to the Federal mental health prohibitor and believed that the proposed rule would exacerbate this problem.

Response: We note that, as a federal agency, the VA is required by law to report prohibited persons to the Attorney General, who oversees the NICS.³³ This final rule does not affect that requirement or change the procedures relating to adjudications that make individuals subject to the Federal mental health prohibitor.³⁴

D. Other Comments

Comment: A few commenters expressed concern that covered entities would misinterpret the proposed permission as a requirement to report information about their

³² See Public Law 110-180, Section 105.

³³ See NICS Improvement Amendments Act of 2007 Sec. 101, 18 U.S.C. 922 note (2002).

³⁴ We refer commenters to the VA regulations for information about the due process afforded to veterans as part of VA competency determinations. See 38 CFR §3.353 and 38 CFR §3.103.

patients to the NICS. Another commenter expressed concern that the standards for reporting NICS data will be adopted by courts as a new standard of care for health care providers, exposing covered entities that do not report to increased liability. The commenter requested that the Department clarify that the HIPAA permission is permissive, not mandatory.

Response: This final rule establishes permission for certain HIPAA covered entities – those with lawful authority to make the adjudications or commitment decisions that make individuals subject to the Federal mental health prohibitor, or that serve as repositories of information for NICS reporting purposes - are permitted to disclose the information needed for these purposes. The rule does not create a requirement to disclose. In addition, as explained at length in the NPRM and above, the rule does not apply to most treating providers, but only to those covered entities that are responsible for the involuntary commitments or other adjudications that make individuals subject to the Federal mental health prohibitor, or that serve as repositories of such data. However, we note that covered entities have a responsibility to comply with all applicable laws, and this final rule does not preempt State or other laws that may require reporting to the NICS.

Comment: One commenter recommended that the Department evaluate whether the rule would have the unintended consequence of permitting the reporting of individuals based on mere medical findings.

Response: As we explain above, the rule does not create a broad permission for treating providers to report information about their patients to the NICS. Rather, the rule is narrowly tailored to permit limited disclosures of information about individuals who

are subject to the Federal mental health prohibitor, which applies only where an individual has been involuntarily committed or otherwise has received a relevant adjudication from a court, board, commission, or other lawful authority.

Comment: One commenter recommended training for the workforce members of reporting entities to ensure that they understand the applicable reporting protocols sufficiently to avoid making erroneous reports.

Response: We agree that training is generally beneficial to assure compliance with applicable standards. Further, to the extent that reporting entities also are HIPAA covered entities, the Privacy Rule requires those entities to train workforce members on the policies and procedures with respect to the privacy and security of individuals' health information. Where applicable, such training would include ensuring that workforce members have copies of the entity's policies and procedures implementing this final rule's limited permission for uses or disclosures of PHI for NICS reporting purposes.

Comment: One commenter recommended establishing a mechanism to inform mental health patients and their caregivers about the patients' status in the NICS.

Response: We decline to provide for such a mechanism in this final rule because it is outside the scope of the rule. Nothing in this rule, however, precludes covered entities from informing individuals that information about them has been provided to the NICS.

Comment: Several commenters expressed concern that, by allowing multiple entities within a State to report to the NICS, the proposed rule would create complexity, inaccuracy, and delay in processing appeals, particularly if the FBI refers the individual back to the reporting entity for resolution.

Response: To the extent that the involvement of multiple entities in NICS reporting may affect the appeals process in a state, this issue exists apart from HIPAA. Each State determines the entity or entities responsible for reporting NICS data, depending on where the records documenting a person's status as subject to one or more of the Federal prohibitors are created or maintained. As a result, a variety of entities, including judicial, law enforcement, public health, and other entities in a State, already may be involved in NICS reporting and appeals.

Comment: A few commenters expressed concern that, as a result of the proposed rule, some families may choose not to seek involuntary commitment proceedings for a family member who needs treatment, but whose livelihood depends on the ability to possess a firearm (e.g., first responders and members of the military), because the commitment would result in a report to the NICS and the loss of the patient's livelihood.

Response: We note that the Federal mental health prohibitor makes the purchase or possession of firearms by prohibited individuals unlawful regardless of whether an individual is reported to the NICS, and this final rule does not change who is subject to the Federal mental health prohibitor. This final rule also does not affect law enforcement and military entities' authorities with respect to making their workforce decisions.

Comment: One commenter asked whether covered entities are obligated to update information they have submitted to the NICS when an individual's circumstances change.

Response: Section 102(c)(1)(B) of the NIAA requires States to update, correct, modify, or remove a record from the NICS if they determine that the person is not prohibited or has received "relief from disabilities" under the mental health prohibitor.

Comment: A number of commenters argued that the proposed regulation would contravene congressional intent, arguing that Congress did not intend to change HIPAA protections for NICS purposes. The commenters stated that legislation on this topic had been considered and rejected and specifically cited S. 649 (the “Fix Gun Checks Act”), which was considered by the Senate on April 18, 2013, but did not receive a vote.

Similarly, some commenters asserted that Congress could have included any desired changes to HIPAA when it passed the NICS Improvements Amendments Act, but did not do so. Therefore, the commenters argued, Congress did not intend to modify HIPAA for NICS reporting purposes.

Response: That Congress did not enact S. 649 does not provide relevant evidence of congressional intent with respect to the scope of the HIPAA Privacy Rule. The absence of a provision in the NIAA to modify HIPAA does not imply that Congress intended to prevent any revisions of the HIPAA Privacy Rule with respect to the NICS. The HIPAA statute confers broad authority on the Department to specify the permitted uses and disclosures of PHI by HIPAA covered entities, and NIAA does not affect this statutory authority.

Comment: Several disability rights organizations asserted that the proposed rule did not provide sufficient evidence of HIPAA barriers to reporting in any State to fulfill a requirement of the Administrative Procedure Act (APA) that there be a rational connection between the facts found by a Federal agency through the rulemaking process and the regulatory choice made.³⁵

³⁵ 5 U.S.C. Subchapter II.

Response: We disagree with the commenters. As stated above, we understand from other comments that at least seven States currently rely on HIPAA covered entities (such as mental health facilities) to report Federal mental health prohibitor data to the NICS. These seven States have laws regarding such reporting, but other States may not. To the extent that any other State does not require NICS-related disclosures by law and the State has not enacted legislation addressing the problem, the Privacy Rule, prior to the effective date of this final rule, would have prevented such disclosures by HIPAA covered entities that do not have hybrid entity status.³⁶ Therefore, there are sufficient data demonstrating that HIPAA's disclosure restrictions can be a barrier to NICS reporting, and thus to the development of an accurate and comprehensive NICS database. The data support finalizing this modification to the Privacy Rule, which removes barriers while limiting the circumstances under which covered entities may disclose PHI to the NICS and limiting the types of PHI that may be disclosed.

We know of one State in particular in which the Privacy Rule's disclosure restrictions posed challenges for NICS reporting. The State of New York had a statute requiring mental health facilities in the State to report NICS data to the State mental health agency, the State's designated repository of NICS data.³⁷ As a result, the Privacy Rule permitted such disclosures to the repository as required-by-law disclosures. However, the statute did not expressly require the mental health agency, which was a covered entity under HIPAA that did not have hybrid entity status, to report the data it

³⁶ We note that at least three states have laws permitting, but not requiring the disclosure of mental health records to the NICS: Missouri, New Jersey and West Virginia. See Mo. Rev. Stat. 630.140 (2013); N.J. Stat. Ann. 30:4-24.3 (2013); W.Va. Code 61-7A-3 (2013).

³⁷ 2008 N.Y. Laws 491, codified at N.Y. Mental Hyg. §§ 7.09(j); 13.09(g), 31.11(5), 33.13(b), (c) (2011); N.Y. Jud. Ct. Acts § 212(q) (2011).

collected to the NICS; the Privacy Rule thus did not permit the agency to disclose this data. Ultimately, the legislature needed to revise the statute to expressly require the agency to report the data to the NICS.³⁸

In addition to removing barriers, an additional benefit of the rule as described more fully below is that it provides clarity about the applicability of the Privacy Rule and its relationship to State law in this area, as well as provides an avenue for NICS reporting that may obviate the need to enact legislation at the State level.

Comment: One commenter requested that the Department clarify how HIPAA's preemption provisions would apply to State laws requiring or prohibiting covered entities' disclosures of NICS data.

Response: We clarify that this final rule does not change HIPAA's existing preemption provisions, which provide that the HIPAA rules preempt contrary State laws (with certain exceptions, such as where the contrary provision of State law is more stringent than the HIPAA provision).³⁹ Accordingly, because the Privacy Rule, as modified by this final rule, only permits (but does not require) the disclosure for NICS reporting purposes, State laws that prohibit such disclosures are not contrary to the Privacy Rule, and covered entities in States with such laws remain subject to any applicable prohibitions against the disclosures under State law. That is, the covered entity could comply with both HIPAA and such State law by not disclosing PHI to the NICS.

³⁸ NY Secure Ammunition and Firearms Enforcement (SAFE) Act of 2013.

³⁹ See 45 CFR 160.203.

Moreover, HIPAA contains an express permission for disclosures that are required by other law, such as State law. Accordingly, State laws that require disclosures, for any purposes, remain in effect, as such laws are not contrary to the Privacy Rule.

Comment: One commenter expressed concern that the rule would create an opportunity for the abuse of private information, for example, by allowing the government to disarm political dissidents who seek mental health care, or making it possible for medical personnel to abuse their authority and remove an individual's rights for illegitimate reasons.

Response: Concerns about governmental or private actors taking advantage of this permission to target vulnerable persons are addressed by the procedural framework built into the statute that established the Federal mental health prohibitor and its implementing regulations, which this final rule does not change. As we previously have noted, the Federal mental health prohibitor, which makes an individual reportable to the NICS, applies only to the extent that the individual is involuntarily committed or determined by a court, board, commission, or other lawful authority to be a danger to self or others, or is unable to manage his or her own affairs due to a mental illness or condition.⁴⁰ These involuntary commitments and other adjudications are not made independently by individual health care providers without any form of official legal review.

Comments: Some commenters expressed concern that, by relaxing HIPAA's privacy requirements, the proposed rule could result in increased disclosures of private health information to the government. Several commenters argued that the Federal government has a poor record on protecting individuals' privacy and should not be

⁴⁰ 18 USC 922(g)(4); 27 CFR 478.11.

entrusted with health information. In contrast, another commenter noted that Federal law, including the Privacy Act, prohibits access to the information in the NICS database outside of the limited purposes authorized by law, and information about specific firearms transfers is destroyed the day after the transaction.

Response: We agree that it is important to protect the privacy and security of the information that is reported to the NICS and we note that the NICS is subject to specific privacy and security protections.⁴¹ In addition, we again emphasize that only very limited information may be disclosed under this rule, and disclosures of diagnostic or clinical information are expressly prohibited.

Comment: Finally, one commenter requested clarification on whether, in States where a covered entity is also a lawful authority that orders involuntary commitments or conducts other adjudications that make individuals subject to the Federal mental health prohibitor, there is intended to be a separation between the covered entity and lawful authority functions of the entity.

Response: We note that, under the Privacy Rule, both before and after the modification made in this final rule, a covered entity could provide for such separation by operating as a hybrid entity, and disclose information through its non-HIPAA covered NICS reporting unit. However, it is our understanding that some covered entities may be unable to achieve hybrid entity status for administrative or other reasons. This is another reason for including the express permission described in the final rule.

VI. Regulatory Analyses

A. Introduction

⁴¹ See 63 FR 58303 (October 30, 1998), codified at 28 CFR part 25.

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 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 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 final rule does not contain any new requirements or prohibitions for covered entities, we estimate that the rule will be cost

neutral. We did not receive public comments on this assumption or information indicating that covered entities will incur any costs 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 final rule.

2. Entities Subject to the Rule

This final rule applies 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. 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. In addition, even covered entities in some states will not be affected because they currently do not face HIPAA barriers to reporting either because state law requires reporting or they have created hybrid entities, as described above in the preamble. We did not receive public comments on the number of covered entities that will be affected by this rule.

B. Why is this rule needed?

This final 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. This rule change can help further the important public safety goal of strengthening the background check system to ensure that individuals who are prohibited from purchasing or possessing firearms are not able to obtain them. 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 and does not become a hybrid entity. Importantly, the final rule permits 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 permits 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 is cost neutral with respect to HIPAA covered entities. The rule does not require entities that already have a NICS reporting process in place to change their current system and does not create new reporting or recordkeeping requirements for any covered entity. The small number of covered entities that are newly permitted to report to the NICS or a State repository under the rule can begin to report 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 are attributable to the choice made by an entity to report information, the Federal statutory mental health prohibitor, and the NICS system itself. See 28 CFR Part 25, Subpart A. 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 does not require any changes to existing HIPAA policies and procedures. In addition, with respect to training, the rule does not require workforce training beyond what is already required under the HIPAA Privacy and Security Rules. We expect that entities that choose to report under the rule would also take steps to ensure that their office staff have copies of the new policies and procedures, which would not involve any significant additional costs. We did not receive public comments contradicting these assumptions or estimating the number of entities that might begin to report to the NICS for the first time, if any.

To the extent that the rule permits 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. Therefore, 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 attributable to the Federal mental health prohibitor and 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 prohibitor “relief from disabilities” programs pursuant to the NICS Improvement Amendments Act of 2007 vary.

We received a number of comments on the NPRM 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, many of these commenters expressed the mistaken belief that the permission would allow or require most mental health care providers to report their patients to the NICS.

As explained above, we have carefully and narrowly tailored the final 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. The rule generally maintains a separation between treatment functions and NICS reporting functions. In addition, the rule does not permit the use or disclosure of any diagnostic or clinical information, or any other information about an individual that is not needed for NICS reporting purposes. Because of these strict limitations on the permitted uses and disclosures, we believe that individuals will not be dissuaded from seeking needed mental health care services as a result of the rule.

Finally, we recognize the intangible burden to individuals of the negative attitudes and misperceptions associated with mental health conditions. We note that the Federal mental health prohibitor does not apply to all individuals with mental health conditions, but instead to a subset of individuals who have been involuntarily committed or determined by a 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. This rule permits 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 facilitates the enforcement of prohibitions that were established by the Gun Control Act. Therefore, we do not expect that this rule will exacerbate negative attitudes or misperceptions associated with mental health conditions.

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, by removing a barrier to reporting, 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 permits covered entities to report those individuals' identities for NICS purposes, the rule provides a public safety benefit. One comment submitted in response to the NPRM noted that increased reporting could contribute to lowering the substantial financial costs of gun violence itself, which was estimated at \$174 billion in medical and lost productivity expenses in 2010.⁴² 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, nor do we have a basis for estimating the impact, if any, on the financial costs associated with gun violence.

An additional benefit of the rule is that it provides clarity about the applicability of the Privacy Rule and its relationship to State law. Specifically, the rule alleviates the

⁴² This comment cited Miller TR. *The Cost of Firearm Violence*. Children's Safety Network Economics and Data Analysis Resource Center, at Pacific Institute for Research and Evaluation, December 2012.

concerns of State lawmakers who, according to several commenters on the ANPRM, may be reluctant to pursue State 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, and thus would not preempt a State law requiring disclosures to NICS. However, to the extent that State lawmakers harbor this misconception, this preamble clarifies HIPAA's preemption provisions and the final rule provides an avenue for NICS reporting that may obviate the need to enact legislation at the State level.

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 either to certify that the rule will not impose such a burden or to 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 will result in compliance costs for covered entities of any size because the rule does not impose new requirements. Therefore, the Secretary certifies that the rule will not have a significant impact on a substantial number of small entities.

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 \$141 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 rule does 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 final rule does 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 are not affected by this rule.

One commenter argued that a permission for entities other than States to report to the NICS would bypass the decisions of the States regarding the submission of reports and, therefore, raises federalism implications. In response, we again emphasize that this rule does not require covered entities to make disclosures that are prohibited by State law, nor does it prevent disclosures required by State law. Further, States retain discretion to determine which entities within the State are authorized to report information to the NICS. For these reasons, the rule does 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, we expect that the rule is cost neutral. We did not receive public comments on any unanticipated costs associated with the rule, including costs to covered entities that choose to amend written HIPAA policies and procedures or to provide additional training to staff.

VII. Collection of Information Requirements

This final rule does not contain requests or requirements to report information to the government, nor does it impose new requirements for recordkeeping or disclosures to third-parties or the public. Therefore, the requirements of the Paperwork Reduction Act with respect to information collections do not apply.

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 amends 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); and

(ii) Discloses the information only 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.

* * * * *

Dated: December 30, 2015.

Sylvia M. Burwell,

Secretary.

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