ABHW
Advancing Health Care Policy
for Mental Health and Addiction

SUMMARY OF KEY PROVISIONS OF THE NPRM TO AMEND 42 CFR PART 2

On December 2, 2022, the U.S. Department of Health and Human Services (the "Department") released a notice of proposed rulemaking[1] ("NPRM") to solicit public comment on its proposal to modify its regulations to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act. This NPRM would primarily amend confidentiality requirements for substance use disorder ("SUD") patient records under 42 C.F.R. Part 2 and would also make minor corresponding amendments to the Privacy, Security, Breach Notification, and Enforcement Rules that implement the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Rules"). Comments on this proposed rule are due to the Department by January 31, 2023.

Part 2 currently imposes different requirements for substance use disorder ("SUD") treatment records protected by Part 2 ("Part 2 records") than the HIPAA Rules, which apply to protected health information ("PHI"). These two statutory and regulatory schemes apply to different types of entities and create dual obligations and compliance challenges for HIPAA covered entities and business associates that maintain PHI and Part 2 records, and, thus, are subject to both sets of rules. Treatment providers have also expressed concerns that they lack access to complete information when treating patients. The CARES Act modified the federal statute governing Part 2 records to align certain Part 2 requirements more closely to the requirements of the HIPAA Rules in order to improve the ability of entities that are subject to Part 2 to use and disclose Part 2 records.

Key proposed revisions to the privacy protections for SUD treatment records include:

(1) Revisions to definitions of key terms under Part 2 to align with definitions from the HIPAA Rules
(2) New or modified requirements for patient consent and redisclosure of Part 2 records
(3) New rights to obtain an accounting of disclosures made with consent and to request restrictions on disclosures
(4) Updates to the Notice of Privacy Practices ("NPP") requirements in the HIPAA Privacy Rule ("Privacy Rule") at 45 CFR 164.520 to address uses and disclosures of Part 2 records and individual rights with respect to those records
(5) New requirements to impose breach notification obligations
(6) New civil money penalties ("CMPs") for violations of Part 2
(7) Greater restrictions against the use and disclosure of Part 2 records in civil, criminal, administrative, and legislative proceedings against patients

[1] Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74216 (Dec. 2, 2022).

Prepared by Epstein Becker Green, PC

FIRM:57556125v1

(8) A new limitation on liability for government agencies that investigate and prosecute Part 2 programs and unknowingly receive records subject to Part 2.

Key details regarding these proposed revisions are described below. A comprehensive summary table of all of the proposed changes and a redline display of the impact of the proposed changes on the regulatory text are provided as attachments.

I. Revisions to definitions of key terms under Part 2 to align with definitions from the HIPAA Rules (§ 2.11)

Summary:

The Department proposes to add thirteen defined regulatory terms and modify the definitions of ten existing terms. **Most of the proposed terms and definitions would be added or modified by referencing existing HIPAA regulatory terms** in 45 CFR parts 160 and 164, either as required by the CARES Act or as a logical outgrowth of CARES Act amendments. **The proposals seek to make clear the specific components of the relevant HIPAA statutory and regulatory provisions that would be incorporated into the Part 2 rule**.

The proposed rule adds new terms and definitions to align with the following statutory and regulatory HIPAA terms: Breach, Business associate, Covered entity, Health care operations, HIPAA, HIPAA regulations, Payment, Person, Public health authority, Treatment, Unsecured protected health information, and Use. The proposed rule creates new defined terms for: Intermediary, Investigative agency, and Unsecured record. The proposed rule modifies the existing definitions of the following terms: Informant, Part 2 program director, Patient, Program, Qualified service organization, Records, Third-party payer, and Treating provider relationship.

The Department also proposes to modify the definition of Qualified service organization ("QSO") by adding HIPAA business associates to the Part 2 regulatory text. This modification would clarify that HIPAA business associates are QSOs in circumstances when Part 2 records also meet the definition of PHI (i.e., when a Part 2 program is also a covered entity). The HIPAA Rules generally permit disclosures from a covered entity to a person who meets the definition of a business associate (i.e., a person who works on behalf of or provides services to the covered entity) without individual authorization, when based on a business associate agreement that incorporates certain protections. Similarly, the use and disclosure restrictions of this part would not apply to the communications between a Part 2 program and QSO when the information is needed by the QSO to provide services to, or work "on behalf of", the Part 2 program.

Requests for comment:

The Department requests comment on all proposals to add new or modify existing definitions to this Part 2. Specific comments are requested on:

- the benefits and burdens of creating additional privacy protection for SUD counseling notes that are maintained primarily for use by the originator of the notes, similar to psychotherapy

notes as defined in the Privacy Rule (i.e., such notes would be Part 2 records, but could not be disclosed based on a general consent for treatment, payment or health care operations ("TPO"); they could only be disclosed with a separate written consent that is not combined with a consent to disclose any other type of health information);

- whether the modifications to the use of the terms "person" and "individual" provide clarity and promote understanding of when the terms are being used to refer to someone who is the subject of the records at issue under Part 2 and the HIPAA Rules;

- the number and type of third-party payers that would not be considered health plans (and therefore would be subject to limitations on redisclosures of Part 2 records);

- the alignment of the definition of "unsecured record" with "unsecured protected health information" in order to implement the newly required breach notification standards for Part 2 records;

- the proposed definition of "intermediary" and whether, in light of the proposed new permission to disclose records for TPO based on a single prior consent, the requirements for an intermediary should be retained or removed

Comments on a number of other areas may also be of use. Comments may be useful to encourage the Department to create a regulatory definition of "lawful holder." A definition for "lawful holder" could further expand exceptions for the re-disclosure of Part 2 records.

Comments may also be useful regarding the proposal to continue to require intermediaries to be named whenever they are used to exchange Part 2 records. Under this proposal, an intermediary would be a person who has received records, under a general designation in a written patient consent, for the purpose of disclosing the records to one or more of its member participants who has a treating provider relationship with the patient. Another issue on which comments may be useful is whether removing the specific intermediary requirements would significantly diminish the regulatory burden of compliance for intermediary entities and eliminate inconsistencies in the requirements for intermediary and non-intermediary entities that serve TPO functions.

Finally, comments may be useful to address whether the definition of "treatment", as proposed to be revised, including as used in section 2.12(a)(1)(ii), would still apply Part 2 protections to a condition which is identified as having been caused by an SUD.

II. New or modified requirements for patient consent and redisclosure of Part 2 records (§§ 2.31, 2.33, 2.53)

Summary

The required elements of the written authorization forms for Part 2 records are proposed to be modified to more closely track the core elements of a written authorization form under

HIPAA, at 45 CFR 164.508(c). Several of the proposed changes to the language do not substantively change the current requirements, but do modify the wording to align with similar requirements under HIPAA (e.g., changes related to identity of the discloser, description of information to be disclosed, the right to revoke consent, and the expiration of consent). For example, the Department notes in the preamble that once a Part 2 program discloses a record for TPO purposes to a Part 2 program, covered entity, or business associate with prior written consent, a revocation of consent would only be effective to prevent additional disclosures to those entities. In alignment with the Privacy Rule, the proposed wording would clarify that Part 2 regulations do not prevent a recipient Part 2 program, covered entity, or business associate from using the previously disclosed record for TPO, or redisclosing the record.

The proposed rule would also add new substantive requirements for the written authorization, including:

- Where applicable, language indicating a single patient consent is meant to apply for all future uses and disclosures for TPO;
- Where the disclosure is for TPO – a statement that the patient's record may be redisclosed in accordance with HIPAA, except for uses and disclosure for civil, criminal, administrative, and legislative proceedings against the patient;
- A description of purpose statements sufficient for relaying (i) when a patient initiates the consent and elects not to provide a statement of purpose, (ii) when a patient provides consent once for all TPO uses and disclosures; and (iii) when the patient consents to uses or disclosures for fundraising;
- Statements around (i) the potential for the records to be redisclosed and no longer protected by Part 2, and (ii) the consequences of refusal to sign the consent.

Where "disclosure" is referenced, here and throughout, the language would be updated to refer to "use and disclosure" to align with HIPAA and clarify that disclosures *and uses* are subject to the rules.

The proposed rule identifies how a recipient may further disclose Part 2 records related to TPO. Currently Section 2.33 allows disclosure with the written consent of the patient, and if the patient consents to disclosure of their records for payment or health care operations, allows a lawful holder to further disclose those records as necessary for its contractors, subcontractors, or legal representatives to carry out the payment or operations specified in the consent.

The Department proposes to create two categories of redisclosure permissions.

The first category would apply to Part 2 programs, covered entities, and business associates that have received a Part 2 record with consent for TPO. These entities would be permitted to redisclose the records for uses and disclosures as permitted by the Privacy Rule (subject to the limitations of proposed subpart E of Part 2 pertaining to legal proceedings). Thus:

- (1) **Where disclosed for TPO activities to a program, covered entity, or business associate, the recipient may further use or disclose of the records *as permitted under HIPAA*.**

The second category of redisclosure permissions would apply to lawful holders that are NOT business associates, covered entities, or Part 2 programs and have received Part 2 records with written consent. For payment and health care operations purposes, this category would permit the recipient to redisclose the records for uses and disclosures to its contractors, subcontractors, and legal representatives to carry out the intended purpose, also subject to the limitations of proposed subpart E of part 2 pertaining to legal proceedings. However, for treatment purposes, a lawful holder under this provision would not be permitted to redisclose Part 2 records it receives before obtaining an additional written consent from the patient. Thus:

- (2) Where disclosed with a consent given once for all future TPO to a Part 2 program that is NOT a covered entity or business associate, the recipient would be able to further disclose only *as consistent with the consent*.
- (3) Where disclosed for payment or operations activities to a lawful holder that is NOT a covered entity, business associate, or Part 2 program, the recipient would be able to further use or disclose those records *as necessary for its contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent*, on behalf of the lawful holders.

Thus, the proposed rule would prohibit redisclosure for the purposes of treatment by a provider that is not a Part 2 program, covered entity, or business associate (under 2.33(b)(3)), while allowing redisclosure for the purposes of treatment by a provider that is a Part 2 program, covered entity, or business associate (under 2.33(b)(1)).

The proposed rule would also exclude covered entities and business associates from the requirements for a written agreement between a lawful holder and redisclosure recipient, because these entities are already subject to the HIPAA requirements for business associate agreements.

Finally, the proposed rule would amend § 2.53 to add a new paragraph (h), allowing disclosure for health care operations, consistent with the proposed new TPO permission that includes the ability of entities to use or disclose Part 2 records for health care operations with a general consent. Part 2 programs, covered entities, and business associates would therefore be permitted to disclose Part 2 records pursuant to a consent for all future TPO uses and disclosures when a requesting entity is seeking records for activities described in paragraphs (c) or (d) of § 2.53.

Requests for comment:

The Department requests comment on:

- Whether there are other changes that should be made to further align § 2.31 with the Privacy Rule using the Department's general regulatory authority in § 3221(i)(1) of the

CARES Act to "make such revisions to regulations as may be necessary for implementing and enforcing the amendments." For example, the Department specifically requests comment on

  - the extent to which Part 2 programs segment out SUD treatment records considered SUD counseling notes.
  - whether to propose special protection for SUD counseling notes to add a layer of regulatory protection that equates to the protection granted to psychotherapy notes in the Privacy Rule by requiring a separate written consent for their disclosure.

- Whether and to what extent the Department should require Part 2 programs to inform requestors when a preexisting consent exists for disclosure and the scope of such consent for disclosure. This input would be helpful as the Department considers how to facilitate covered entities' abilities to use the new permissions for TPO disclosures and related redisclosures under the Privacy Rule and Part 2.

- The extent to which Part 2 programs accept or rely on oral revocations of consent, and if so, whether and how this is documented or tracked.

- Whether it would be helpful to define the terms "contractors, subcontractors, and legal representatives" and, if so, what definitions would appropriately retain the existing accepted understanding of the business relationships.

- The extent to which the proposed changes to § 2.33 would result in reduction of patient trust that their Part 2 records will be kept confidential and thus affect the ability to provide treatment to patients with SUD.

- How Part 2 programs and recipients of Part 2 records would identify records for which a patient has given consent for TPO uses and disclosures generally as compared to consent for one purpose or a consent limited to certain segments of Part 2 information.

- The ways to increase coordination amongst not only Part 2 programs or recipients of Part 2 records and providers of other healthcare services but also with the health IT developer and HIE communities to protect privacy for Part 2 records within EHRs.

- How the proposed revisions to § 2.33 might affect the future data segregation practices of Part 2 programs and recipients of Part 2 records.

- Whether or how recipients of Part 2 records are informed that the records have been disclosed based on patient consent and the scope of the consent that is provided. Specifically, how Part 2 programs and recipients of Part 2 records communicate information about the purpose of a disclosure or set of disclosures and the extent of the information communicated about the purpose or the scope of the disclosure permission, authorization, or mandate.

- Whether to consider requiring Part 2 programs to provide a copy of the written patient consent when disclosing records

- Whether to consider requiring Part 2 programs, covered entities, and business associates to retain a copy of the written patient consent for a minimum period of time so that they can provide documentation of the consent to future recipients, or to the Secretary for purposes of investigating compliance with Part 2. Are programs already doing this? To what extent would such requirements be useful to recipients of Part 2 records or impose a burden on programs?

- Whether to require programs to inform an HIE when a patient revokes consent for TPO so that additional uses and disclosures by the HIE would not be imputed to the programs that have disclosed Part 2 records to the HIE?

- The potential unintended negative effects on confidentiality and privacy from the combined application of the proposed disclosure permissions for TPO with consent under § 2.33, and the removal of § 2.53 protections for audit and evaluation activities that fall within the definition of health care operations, and suggested regulatory approaches.

- The permission for use and disclosure of records for health care operations purposes based on written consent of the patient for all future uses and disclosures for TPO, and the permission for the third party conducting such audit or evaluation activities to redisclose the records, as permitted by the HIPAA Privacy Rule.

- Whether the new redisclosure permission for Part 2 programs, covered entities, and business associates may create incentives for such recipients to rely on patient consent more frequently when performing audit and evaluation of records made available by Part 2 programs.

III. New rights to obtain an accounting of disclosures made with consent and to request restrictions on disclosures (§§ 2.25, 2.26)

Summary

A newly proposed section would require a Part 2 program to provide to a patient, upon request, an accounting of all disclosures made with consent under § 2.31 in the six years prior to the date of the request.

This section would also require that a Part 2 program provide a patient with an accounting of disclosures of records for treatment, payment, and health care operations under § 2.33 only where such disclosures are made through an electronic health record, and that a patient only has a right to receive an accounting of these disclosures during the three years prior to the date on which the accounting is requested. This proposed right to an accounting of disclosures of records mirrors the standard in the Privacy Rule at 45 CFR 164.528.

Another newly proposed section would incorporate two distinct patient rights into Part 2:

- A patient right to request restrictions on disclosures of records otherwise permitted for TPO purposes; and
- A patient right to obtain restrictions on disclosures to health plans for services paid in full by the patient, including a requirement for Part 2 programs to permit a patient to restrict uses or disclosures of the patient's records to carry out treatment, payment, or health care operations.

A Part 2 program would <u>not</u> generally be required to agree to a requested restriction. However, a Part 2 program would be required to agree to restrict the disclosure of a patient record to a health plan, even for payment or health care operations, if the record pertains solely to an item or service for which the patient has paid in full.

Once a request for a restriction is made, a Part 2 program would not be able to use or disclose the records unless the patient is in need of emergency treatment and the restricted record is needed to provide the treatment. If a record is disclosed to provide emergency care, the program would be required to request that the emergency health care provider not further disclose the information.

A requested restriction would not be effective to prevent uses or disclosures required by law, such as for payment and other health care operations.

A program would only be able to terminate a restriction under certain listed circumstances.

<u>Requests for comment</u>

The Department requests comment on:

- The proposals to add a requirement for an accounting of disclosures for non-TPO disclosures and an accounting of disclosures through an electronic health record for TPO
- The provider burden and costs to respond to a request for an accounting for both TPO disclosures and non-TPO disclosures
- The extent to which covered entities and Part 2 programs receive requests from patients to restrict disclosures of patient identifying information for TPO purposes, how entities and programs track such requests, and the procedures and mechanisms used to comply with patient requests to which they have agreed or that they are otherwise required to comply with by law
- The requirements in redesignated § 2.24 for "intermediaries," including entities that facilitate health information exchanges, and whether there is a continued need for these requirements in light of the accounting of disclosures proposed in § 2.25. Specifically, the Department solicits comment on how Part 2 programs have been implementing the existing requirements for intermediaries in § 2.13(d) and § 2.31(a)(4)(ii) and examples of how those requirements have affected the ability of Part 2 programs to utilize HIEs.

Comments may be useful to support the Department's approach to aligning these requirements with HITECH accounting of disclosure requirements and effective date.

Comments may also be useful to request a safe harbor for redisclosures under TPO with consent by intermediaries made after a request for restriction is submitted to a Part 2 program.

With regard to this section and the Department's request for comments on § 2.24, comments may be useful to address the administrative burden on "intermediaries" and relative value to patients of providing patients with a list of disclosures. One alternative would be to allow for the general listing of entity types that receive redisclosures under general broad designations. Another alternative would be to allow for a more limited or streamlined accounting of disclosures if the disclosure was made under TPO with consent.

IV. Updates to the Notice of Privacy Practices requirements in the HIPAA Privacy Rule to address uses and disclosures of Part 2 records and individual rights with respect to those records (42 CFR § 2.22 and 45 CFR § 164.520)

Summary

The NPRM would significantly change § 2.22 to require all Part 2 programs, at the time of admission, to inform the patient that federal law protects the confidentiality of substance use disorder records. The NPRM also sets forth a detailed set of requirements for the Notice of Privacy Practices that Part 2 programs are required to provide. Notification requirements would now specify interaction between the HIPAA Notice of Privacy Practices and the Part 2 Notice of Privacy Practices.

Requests for comment

The Department requests comment on:

- Ways to make the proposed notices more easily understandable, including examples of possible approaches, such as requiring the document to be at a particular reading grade level, maximum number of pages, or other suggestions.

Comments may also be useful regarding the proposed approach for notification, including implications for network provider agreements.

V. New requirements impose breach notification obligations (§ 2.16)

Summary

The NPRM would apply the HITECH Act breach notification provisions that are currently implemented in the Breach Notification Rule to breaches of records by Part 2 programs. It would also clarify that formal policies and procedures designed to reasonably protect against unauthorized uses and disclosures of patient identifying information must address all issues regarding paper and electronic records listed in this part.

In addition, the proposed rule would apply to breaches by Part 2 programs the provisions of 45 CFR part 160 and subpart D of part164, which require notification in the case of a breach of unsecured protected health information.

For both paper and electronic records, the NPRM would require that de-identified patient identifying information must be rendered in accordance with the requirements of HIPAA at 45 CFR 164.514(b), "such that there is no reasonable basis to believe that the information can be used to identify a particular patient as having or having had a substance use disorder."

Requests for comment

The Department requests comment on:

- The Department's assumptions about the application of the Breach Notification Rule to Part 2 records, including the treatment of disclosure or re-disclosure of Part 2 records outside of Part 2 requirements as a breach and the burden of requiring lawful holders to maintain and follow Part 2 breach identification/response policies and procedures as a condition of compliance.

- Examples of persons who are lawful holders under the existing regulation, such as MCOs, who may not be appropriate to hold liable under the Breach Notification Rules for compliance with the administrative requirements for protecting Part 2 records they have received.

- The need to create a regulatory definition of "lawful holder" and to use that mechanism to further expand exceptions for the re-disclosure of Part 2 records. In particular, it may be useful to comment that a definition of "lawful holder" should provide for a safe-harbor from the imposition of civil or criminal monetary penalties under the Breach Notification Rule for the unintentional re-disclosure of Part 2 records by lawful holders that would have otherwise been a compliant disclosure of PHI under HIPAA TPO.

- Examples of situations in which Part 2 programs or covered entities render Part 2 information not readily identifiable but the information is not de-identified in accordance with the Privacy Rule.

VI. New civil money penalties (CMPs) for violations of Part 2 (§2.3)

Summary

The proposed changes would align Part 2 enforcement and penalties with HIPAA by replacing existing criminal penalties for Part 2 violations with references to the HIPAA enforcement authorities at Social Security Act sections 1176 (related to civil enforcement, including the Civil Monetary Penalty tiers established by the Health Information Technology for

Economic and Clinical Health (HITECH) Act of 2009) and 1177 (related to criminal penalties), thereby establishing specific civil and criminal penalties for violations of the Part 2 rules, as required by the CARES Act. Further, the proposed regulations would apply the HIPAA Enforcement Rule to violations of Part 2 in the same manner as the Enforcement Rule applies to covered entities and business associates for violations of HIPAA.

The proposed rule would further create a safe harbor against civil or criminal liability for persons acting on behalf of investigative agencies when, in the course of investigating or prosecuting a Part 2 program or other person holding Part 2 records (or their employees or agents), the person acting on behalf of the investigative agency may unknowingly receive Part 2 records without first obtaining the requisite court order. This safe harbor would be limited to only instances where records are obtained for the purposes of investigating a program or person holding the record, not a patient.

Investigative agencies would have to follow Part 2 requirements for obtaining, using, and disclosing Part 2 records as part of an investigation or prosecution; such requirements include seeking a court order, filing protective orders, maintaining security for records, and ensuring that records obtained in program investigations are not used in legal actions against patients who are the subjects of the records. The limitation on liability would be available for uses or disclosures inconsistent with Part 2 when the person acted with reasonable diligence to determine in advance whether Part 2 applied to the records or program.
"Reasonable diligence" (as proposed) requires acting within a reasonable period of time, but no more than 60 days prior to, the request for records or placement of an undercover agent or informant. "Reasonable diligence" also includes taking the following actions to determine whether a health care practice or provider (where it is reasonable to believe that the practice or provider provides SUD diagnostic, treatment, or referral for treatment services) provides such services by: (1) checking a prescription drug monitoring program in the state where the provider is located, if available and accessible to the agency under state law; or (2) checking the website or physical location of the provider.

Requests for comment

The Department requests comment on:

- The need for investigation of Part 2 programs and holders of Part 2 records and a related safe harbor for law enforcement due to proposed changes in enforcement of Part 2 requirements
- The impact of the proposed safe harbor on patient privacy and access to SUD treatment
- Situations for which a safe harbor should be considered for SUD providers that unknowingly hold Part 2 records and unknowingly disclose them in violation of Part 2
- The likely benefits and costs of the proposed changes to the enforcement regime under Part 2.

VII. Greater restrictions against the use and disclosure of records in civil, criminal, administrative, and legislative proceedings against patients (§2.13, 2.63, 2.64, 2.65)

Summary

The existing § 2.13 applies confidentiality restrictions and safeguards to how Part 2 records may be "disclosed and used", and specifically provides that Part 2 records may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings. The existing § 2.13 also provides that unconditional compliance is required by programs and lawful holders and restricts the ability of programs to acknowledge the presence of patients at certain facilities.

Revisions are proposed to clarify that the that the confidentiality restrictions and safeguards in this provision apply to both uses and disclosures of Part 2 records.

Existing paragraph (d) of § 2.13 includes a requirement for intermediaries to provide patients with a list of entities to which an intermediary, such as a health information exchange (HIE), has disclosed the patient's identifying information pursuant to a general designation. Under the NPRM, § 2.13(d) would be removed and the contents redesignated as § 2.24. This change is intended to distinguish the right to a list of disclosures made by intermediaries from the proposed new right to an accounting of disclosures made by a Part 2 program.

The NPRM would also specify that civil, as well as criminal, administrative, and legislative proceedings are circumstances under which a court may authorize disclosures of confidential communications made by a patient to a Part 2 program in Part 2 records when the patient opens the door by introducing their records or testimony that relays information in their records as evidence.

Requests for comment

The Department requests comment on:

- The extent to which Part 2 programs look to the HIPAA Security Rule as a guide for safeguarding Part 2 electronic records and whether the same, similar, or other safeguard requirements should apply to electronic Part 2 records as the HIPAA Security Rule applies to ePHI.

Comments may be also useful to address whether there are concerns with applying the HIPAA Security Rule's safeguard requirements to electronic Part 2 records.

VIII. A new limitation on liability for government agencies that investigate and prosecute Part 2 programs and unknowingly receive records subject to Part 2 (§§2.66, 2.67, 2.68)

Summary

The NPRM would amend § 2.66 to add a new paragraph (a)(3) that details procedures for investigative agencies to follow in the event they unknowingly obtain Part 2 records during an investigation or prosecution of a Part 2 program or person holding Part 2 records. Specifically, the Department would require an investigative agency that discovers in good faith that it has obtained Part 2 records to secure the records according to 2.16 and cease using or disclosing them until it obtains a court order authorizing the use and disclosure of the records and any records later obtained.

Proposed § 2.68 would require investigative agencies to file an annual report with the Secretary of the applications filed for court orders after use or disclosure of records in an investigation or prosecution of a program or holder of records under 2.66(a)(3)(ii) and after placement of an undercover agent or informant under 2.67(c)(4).

Requests for comment

The Department requests comment on:

- Creating a limitation on civil and criminal liability for investigative agencies that in good faith discover they have received Part 2 records before obtaining the required court order in the course of investigating or prosecuting a program
- The requirement for investigative agencies that make use of these provisions to submit a report to the Secretary