

CMS-0029-P-1 Exemption of Certain Systems of Records Under the Privacy Act

Submitter : Ms. Amy Nordeng

Date & Time: 07/24/2007

Organization : MGMA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

**Provisions of the Proposed
Rule**

Provisions of the Proposed Rule

CMS-0029-P - Exemption of Certain Systems of Records Under the Privacy Act

CMS-0029-P-1-Attach-1.DOC

CMS-0029-P-1-Attach-1.DOC



July 24, 2007

Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Exemption of Certain Systems of Records Under the Privacy Act [CMS-0029-P]

Dear Ms. Norwalk:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the proposed regulation "Exemption of Certain Systems of Records Under the Privacy Act" as published in the May 25, 2007 *Federal Register*. MGMA commends the Centers for Medicare & Medicaid Services' (CMS) efforts to pursue law enforcement activities while maintaining the privacy and security of information maintained in certain records systems.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA serves nearly 21,000 members who lead and manage some 12,500 organizations in which almost 270,000 physicians practice. MGMA's core purpose is to improve the effectiveness of medical group practices and the knowledge and skills of the individuals who manage and lead them. Its diverse membership is comprised of administrators, CEOs, physicians in management, board members, office managers and many other management professionals. They work in medical practices and ambulatory care organizations of all sizes and types, including integrated systems and hospital- and medical school-affiliated practices.

The Privacy Act governs the federal executive branch's use of individuals' personal information. The current proposal would seek to amend 45 C.F.R. § 5b.11 by exempting the following four systems of records from certain requirements of the Privacy Act: the Automated Survey Processing Environment Complaint/Incidents Tracking System (ACTS), the Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), the Organ Procurement Organizations Systems (OPOS) and the Fraud Investigative Database (FID). As tools of law enforcement investigations, MGMA supports CMS's decision to exempt these particular systems from certain requirements of the Privacy Act to protect the identities of persons contained in these records. Of these databases, MGMA members are particularly concerned with the HITS and FID systems, which may contain MGMA member information, either as the subject of or as a source of information for a government investigation.

As set forth in 45 C.F.R. § 5b.11(c)(2), an individual would still be granted access to a record in an exempt system, "but only to the extent such notification or access would not reveal the identity of a source who furnished the record to the Department under an express promise." However, it is further set out in 45 C.F.R. § 5b.11(d) that a responsible Department official can release those same records at his or her discretion. While 45 C.F.R. §5b.11(c)(2) protects a source from being identified, the release of information under 45 C.F.R §5b.11(d) does not provide similar protections. Given the subject matter of these databases, MGMA is concerned that the exception allowed by 45 C.F.R. §5b.11(d) will not protect its members who report wrongdoing. This is a

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particular concern with respect to the HITS database, which could include MGMA member complaints regarding insurance plans with which they have a contractual relationship. MGMA asks CMS to further amend 45 C.F.R §5b.11(d) so that Department officials do not have the discretion to extinguish protections granted under an express promise by another representative of the Department. Otherwise, there will be no assurances made to the source that his or her identity will be shielded and that he or she will be protected from retaliation based on proper reporting. This could negatively impact the Department's enforcement efforts.

In sum, no party should have the discretion to ignore an express promise by the Department not to reveal the identity of individuals supplying information to CMS. By making this change, CMS could increase the lawful reporting of potential wrongdoing. MGMA appreciates the opportunity to comment on this proposal and supports such regulations when they are done for the purpose of increasing the integrity of the services provided by CMS. If you have any questions, please contact Amy Nordeng in the Government Affairs Department at 202.293.3450 x 1380.

Sincerely,

A handwritten signature in black ink, appearing to read "William F. Jessee". The signature is fluid and cursive, with a long horizontal stroke at the end.

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

CMS-0029-P-2 Exemption of Certain Systems of Records Under the Privacy Act

Submitter : Angela Foehl

Date & Time: 07/24/2007

Organization : American Psychiatric Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-0029-P-2-Attach-1.PDF

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Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code CMS-0029-P
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July 23, 2007

RE: Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act” [CMS-0029-P] RIN 0938-A069, May 25, 2007

Dear Deputy Administrator Kuhn:

The American Psychiatric Association (APA), the national medical specialty society representing more than 38,000 psychiatric physicians, appreciates the opportunity to submit these comments in response to the proposed rule by the Centers for Medicare & Medicaid Services (CMS), entitled “Exemption of Certain Systems of Records Under the Privacy Act,” concerning 45 C.F.R. Part 5b, published in the Federal Register on May 25, 2007.¹ CMS states that, “(t)his proposed rule would exempt the four system of records from subsections (c)(3), (d)(1) through (d)(4), (e)(4)(G) and (H), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). . .”² Through a revised 45 C.F.R. Section 5b.11, all four of these CMS systems of records would be affected in the same manner:

1. *The Automated Survey Processing Environment (ASPEN) Complaint/Incidents Tracking System (“ACTS”)* HHS/CMS, System No. 09-70-0565;³

¹ Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act;” [CMS-0029-P] RIN 0938-A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)].

² Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act;” [CMS-0029-P] RIN 0938-A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)], “Summary” at 29289.

³ Centers for Medicare & Medicaid Services (CMS) Notice of a modified or altered System of Records (SOR): “Privacy Act of 1974; Report of a Modified or Altered System of Records;” [Federal Register Vol. 71, No. 99 (May 23, 2006)], announcing the intent to modify the “Automated Survey Processing Environment (ASPEN) Complaints/ Incidents Tracking System (ACTS), System No. 09-70-1519.”

2. *The Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System* (“HITS”), HHS/CMS, System No. 09–70–0544;⁴
3. *The Organ Procurement Organizations System* (“OPOS”), HHS/CMS, System No. 09–70–0575;⁵ and
4. *The Fraud Investigation Database* (“FID”), HHS/CMS, System No. 09–70–0527.⁶

Scope of Proposed Exemptions

CMS intends to revise 45 C.F.R. Section 5b.11 to exempt these four systems from a variety of protections for individuals and agency requirements established by the Privacy Act, 5 U.S.C. Section 552a. CMS’ authority for the proposed rule is Privacy Act Section 552a(k) “Specific exemptions.”⁷ The proposed CMS exemption, per revised Section 5b.11, is intended to cover records in all four of the *systems*.⁸ A “system of

⁴ Centers for Medicare & Medicaid Services (CMS) Notice: “Privacy Act of 1974; Report of a New System of Records;” [Federal Register Vol. 70, No. 128 (July 6, 2005)], announcing a new system of records titled, “Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), System No. 09–70–0544”

⁵ Centers for Medicare & Medicaid Services (CMS) Notice: “Privacy Act of 1974; Report of a New System of Records;” [Federal Register Vol. 71, No. 98 (May 22, 2006)], announcing a new System of Records (SOR) titled, “Organ Procurement Organizations System (OPOS), System No. 09–70–0575.”

⁶ Centers for Medicare & Medicaid Services (CMS) Notice: “Privacy Act of 1974; Report of a Modified or Altered System of Records;” [Federal Register Vol. 71, No. 248 (December 27, 2006)], announcing the intent to modify the “CMS Fraud Investigation Database (FID), System No. 09–70–0527.”

⁷ Privacy Act, 5 U.S.C. § 552a(k) “Specific exemptions

The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553(b)(1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) of this section if the system of records is--

(1) subject to the provisions of section 552(b)(1) of this title;

(2) investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of this section: Provided, however, That if any individual is denied any right, privilege, or benefit that he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence. . . .”

⁸ Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act;” [CMS–0029–P] RIN 0938–A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29289:

“(t)his proposed rule would exempt the four system of records from subsections (c)(3), (d)(1) through (d)(4), (e)(4)(G) and (H), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). . . .”

and at 29291:

“We propose to exempt the ACTS, HITS, OPOS, and FIS systems of records from subsection (c)(3), (d)(1) through (d)(4), (e)(4)(G) and (H), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2).”

records” is defined in the Privacy Act and comprises all records with identifiers within each system.⁹

Section 552a(k) restricts the scope of CMS’ proposed specific exemption, Section 5b.11, to the provisions of Privacy Act subsections (c)(3), (d)(1) through (d)(4), (e)(4)(G) and (H), and (f). None of these are themselves exemptions. CMS correctly states in its proposed rule that, “(t)hese exemptions apply only to the extent that information in a record is subject to exemption pursuant to 5 U.S.C. 552a(k)(2).”¹⁰ This statement suggests that CMS acknowledges some limitations to its proposed exemption, yet it does not address what those might be.

Limitations on Section 552a(k) “Specific Exemptions”

Three limitations exist within Section 552a(k) that allow agencies to make “specific exemptions” that exempt systems of records from certain Privacy Act provisions. Two limitations involve the type and purpose of the material. Those records must be “investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2).”^{11, 12} Subsection (j)(2) allows criminal law enforcement agencies to make general exemptions. If the material is *not* “investigatory” or “compiled for law enforcement purposes,” such material is outside the scope of an

⁹ Privacy Act, 5 U.S.C. § 552a. “Records maintained on individuals

(a) Definitions . . .

(5) the term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. . .”

¹⁰ Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act;” [CMS–0029–P] RIN 0938–A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29291.

¹¹ Privacy Act, 5 U.S.C. Section 552a:

“(k) Specific exemptions

The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553(b)(1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) of this section if the system of records is--

(1) subject to the provisions of section 552(b)(1) of this title;

(2) investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of this section. . .”

¹² Privacy Act, 5 U.S.C. Section 552a:

“(j) General exemptions

The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553(b)(1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from any part of this section except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i) if the system of records is--

(1) maintained by the Central Intelligence Agency; or

(2) maintained by an agency or component thereof which performs as its principal function any activity pertaining to the enforcement of criminal laws. . .”

exemption created under 5 U.S.C. 552a(k)(2). Records must meet both tests in order to fall under that type of exemption.

The third (k)(2) limitation protects the individual's rights from being abridged by an agency's Section 552a(k) special exemption. Subsection (k)(2) mandates that *an individual's rights, privileges or benefits under Federal law cannot be denied through exercise of the exemption*, except if disclosure of material "would reveal the identity of a source who furnished information to the Government under an express (or implied) promise," depending on its date.

One serious concern is that CMS does not address any of these three limitations within the proposed rule's narrative text or regulatory language, except indirectly. Using this as justification for the exemption, CMS refers to agency assurance of informant confidentiality being connected to records access disputes:

"In the course of investigations, we often have a need to obtain confidential information involving individuals other than the individual who is the subject of the file. In these cases, it is necessary for us to preserve the confidentiality of the information to avoid unwarranted invasions of personal privacy and to assure recipients of Federal financial assistance that this information will be kept confidential. This assurance is often central to resolving disputes concerning access by CMS to the recipient's records. . . ."¹³

While CMS recognizes the need to prove a promise of identity confidentiality to an informant in order to resolve Privacy Act access disputes, CMS does not address this within the regulatory language. CMS does not establish any definitions, criteria, guidelines or other means to effectuate this confidentiality promise, determine its effective date, or to recognize whether or not a promise has been effectuated for subsection (k)(2) purposes. There is nothing in the existing Privacy Act regulations, including 5b.1 definitions, Section 5b.11 "Exempt Systems" that addresses this issue.

Without a cogent method for determining whether a valid confidentiality promise exists for the purpose of exercising a (k)(2) exemption, the individual is left to seek judicial interpretation of this matter. Considering the substantial effect of this issue on the Privacy Act rights of individuals, it would be highly advantageous for CMS to adopt language within this regulatory scheme that will clarify what such a promise is, how it is made and how it is documented.

CMS Rationale for Proposed Rule

¹³ Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Exemption of Certain Systems of Records Under the Privacy Act," [CMS-0029-P] RIN 0938-A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29291.

In the notice, CMS repeats verbatim the same, short rationale paragraph under each of the Privacy Act subsections it means for the proposed rule to exempt.¹⁴ CMS' rationale is that:

“Disclosure of confidential information to the subject individual could impede ongoing investigations, invade the personal privacy of individuals, reveal the identities of confidential sources, or otherwise impair our ability to conduct investigations.”¹⁵

Examples of investigatory impedance or impairment resulting from the current regulatory scheme are not offered. Presumably, CMS could invoke confidentiality as a legitimate reason to avoid revealing an informant's identity, even without a regulatory exemption. Documentation of an agency promise to the informant to keep identity confidential would be required with or without an exemption. A special exemption could invoke subsection (k)(2)'s provision that allows an agency to abridge an individual's federal rights with regard to records, to the extent required to protect informant confidentiality.¹⁶ However, the proposed rule does not refer to this provision to protect Privacy Act rights, despite an exemption, or to the informant confidentiality issue.

CMS does not seem to have considered a more narrowly tailored exemption that would differentiate law-enforcement records that really justify a decreased level of Privacy Act protections from ordinary records that do not. If informant identifiers are the main issue, electronic records make it easier than ever to redact identifiers for informants quickly and easily before disclosing records.

¹⁴ Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act;” [CMS-0029-P] RIN 0938-A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29291.

¹⁵ Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act;” [CMS-0029-P] RIN 0938-A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29291.

¹⁶ Privacy Act, 5 U.S.C. Section 552a:

“(k) Specific exemptions

The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553(b)(1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) of this section if the system of records is--

(1) subject to the provisions of section 552(b)(1) of this title;

(2) investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of this section: Provided, however, That if any individual is denied any right, privilege, or benefit that he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;”

CMS does not differentiate among the perceived problems or anticipated benefits from the proposed rule that relate to each Privacy Act subsection, even each covers different individual rights and agency requirements. Those include: (c)(3): disclosure information; (d)1-4: individual's access to and amendment of records with due process; (e)(4)(G) and (H): agency requirements to publish notice about records systems, procedures for individuals to get notice if records pertain to him or her, and how to gain access to those records; and (f): requirement of an agency to promulgate rules covering an individual's notice of, access to and ability to amend records with due process procedures. Considering that this proposed exemption has rather sweeping implications, it would be welcome if CMS would more fully explain conceptual connections among its concerns, these Privacy Act subsections and the proposed exemption.

CMS Does Not Define “Investigative Materials” or “Law Enforcement Purposes”

The proposed rule broadly characterizes records in these systems as “investigative materials,” in order to fall within the statutory authority of Section 552a(k) that allows regulatory exemptions for “investigatory material compiled for law enforcement purposes.”¹⁷ This term consolidates two separate tests that the records must meet, in order to invoke the proposed exemption: 1) whether the records are “investigative materials;” and 2) whether these records are “compiled for law enforcement purposes.”

CMS does not distinguish in this proposed rule which records in these systems meet this description and which do not. A definition for “investigative materials” does not appear in the proposed regulation or in current Privacy Act regulations, including Section 5b.1 “Definitions.” A definition for this term is essential and should be part of the regulatory scheme. Absent a definition, CMS has full discretion as to what this means, which may lead to litigation to interpret the term's meaning and whether the regulatory exemption can apply.

Distinguishing Records Types within Systems

¹⁷ Centers for Medicare & Medicaid Services (CMS) Proposed Rule: “Exemption of Certain Systems of Records Under the Privacy Act,” [CMS-0029-P] RIN 0938-A069 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29292:

“§ 5b.11 Exempt Systems

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(H) Investigative materials compiled for law enforcement purposes from the Automated Survey Processing Environment (ASPEN) Complaints/Incidents Tracking System (“ACTS”), HHS/CMS.

(I) Investigative materials compiled for law enforcement purposes from the Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (“HITS”), HHS/CMS.

(J) Investigative materials compiled for law enforcement purposes from the Organ Procurement Organizations

System (“OPOS”), HHS/CMS.

(K) Investigative materials compiled for law enforcement purposes from the CMS Fraud Investigation Database

(“FID”), HHS/CMS.”

There are seven CMS records systems currently subject to a subsection (k)(2) exemption under 45 C.F.R. 5b.11(b)(2)(ii)(A-G), as well as two other systems subject to a (j)(2) exemption, under 45 C.F.R. 5b.11(b)(2)(i)(A-B), for a total of nine systems. Adding four more systems through this proposed rule would make a total of thirteen records systems at CMS that are under blanket Privacy Act subsection (j)(2) or (k)(2) exemptions, despite CMS' regulatory policy to create exemptions only in "compelling cases" and to protect individuals' privacy "to the fullest extent possible."¹⁸ Within 5b.11, none of these systems are subcategorized into records types that could fall outside of the exemptions.

CMS does not distinguish records in these systems that could be outside the exemption, i.e., those without informant identifiers; those not truly "investigative materials" or those not being used for "law enforcement purposes." All kinds of records within these four systems are lumped together for a systems exemption. Apart from static records types, the character, status and purpose of records may change over time. For instance, complaints filed but not investigated, closed for lack of merit, or found in favor of the provider are not necessarily currently used for "law enforcement purposes." The regulation proposed does not address any of these issues that could potentially preclude the exemption from applying and this is not resolved in 45 C.F.R. 5b.11.

Purpose of Systems and Intended Non-Law Enforcement Disclosure Purposes

In its 2005 notice of the new HIPAA information system (HITS), CMS specified a list of intended records disclosure purposes apart from the main purpose that concerns complaint investigations:

"Information retrieved from this SOR will also be disclosed to: (1) Support regulatory, *reimbursement, and policy functions performed within the agency*, HIPAA entities, or by a contractor or consultant; (2) assist another Federal or state agency in the enforcement of HIPAA regulations where sharing the information is necessary to complete the processing of a complaint, *contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or enable such agency to administer a Federal health benefits program*; (3) *support constituent requests made to*

¹⁸ CMS Privacy Act regulations 45 C.F.R. Part 5b:

§ 5b.3 Policy.

"It is the policy of the Department to protect the privacy of individuals *to the fullest extent possible* while nonetheless permitting the exchange of records required to fulfill the administrative and program responsibilities of the Department, and responsibilities of the Department for disclosing records which the general public is entitled to have under the Freedom of Information Act, 5 U.S.C. 552, and Part 5 of this title." *(Italics added)*

§ 5b.11 Exempt systems.

(a) *General policy.* The Act permits certain types of specific systems of records to be exempt from some of its requirements. It is the policy of the Department to exercise authority to exempt systems of records *only in compelling cases.*" *(Italics added)*

*a congressional representative; (4) support litigation involving the agency; and (5) combat fraud and abuse in certain health benefits programs.*¹⁹ (*Italics added*)

In May 2006, CMS announced a second, new system, the “Organ Procurement Organizations System” (OPOS).²⁰ The day after the OPOS notice, CMS published a modification notice for ACTS.²¹ Later in 2006, CMS published a notice of intent to modify the Fraud Investigation Database (FID) System.²² CMS used a similar list of

¹⁹ Centers for Medicare & Medicaid Services (CMS) Notice of a new System of Records (SOR): “Privacy Act of 1974; Report of a New System of Records;” [Federal Register Vol. 70, No. 128 (July 6, 2005)], announcing a new system of records titled, “Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), System No. 09–70–0544,” at 38944:

“The purpose of this system is to store the results of all OESS regional investigations, to determine if there were violations as charged in the original complaint, to investigate complaints that appear to be in violation of the Transactions and Code Sets, Security, and Unique Identifier provisions of HIPAA, to refer violations to law enforcement activities as necessary, and to maintain and retrieve records of the results of the complaint investigations.”

²⁰ Centers for Medicare & Medicaid Services (CMS) Notice: “Privacy Act of 1974; Report of a New System of Records;” [Federal Register Vol. 71, No. 98 (May 22, 2006)], announcing a new System of Records (SOR) titled “Organ Procurement Organizations System (OPOS), System No. 09–70–0575” at 29336:

“The purpose of this system is to collect and maintain individually identifiable information pertaining to complaint allegations filed by a complainant, beneficiary, or providers of services made against OPOs, information gathered during the complaint investigation, findings and results of the investigation, and correspondence relating to the outcome of the investigation. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency, or by a contractor, consultant or grantee; (2) assist another Federal or state agency in the enforcement of OPO regulations where sharing the information is necessary to complete the processing of a complaint, contribute to the accuracy of CMS’s proper payment of Medicare benefits, and/or enable such agency to administer a Federal health benefits program; (3) support constituent requests made to a Congressional representative; and (4) support litigation involving the agency.”

²¹ Centers for Medicare & Medicaid Services (CMS) Notice of a modified or altered System of Records (SOR): “Privacy Act of 1974; Report of a Modified or Altered System of Records;” [Federal Register Vol. 71, No. 99 (May 23, 2006)], announcing the intent to modify the “Automated Survey Processing Environment (ASPEN) Complaints/ Incidents Tracking System (ACTS), System No. 09–70–1519,” at 29644:

“The primary purpose of this modified system is to track and process complaints and incidents reported against Medicare and/or Medicaid certified providers and suppliers, and CLIA-certified laboratories, these include: skilled nursing facilities, nursing facilities, hospitals, home health agencies, end-stage renal disease facilities, hospices, rural health clinics, comprehensive outpatient rehabilitation facilities, outpatient physical therapy services, community mental health centers, ambulatory surgical centers, suppliers of portable X-Ray services, and intermediate care facilities for persons with mental retardation.

²² Centers for Medicare & Medicaid Services (CMS) Notice: “Privacy Act of 1974; Report of a Modified or Altered System of Records;” [Federal Register Vol. 71, No. 248 (December 27, 2006)], announcing the intent to modify the “CMS Fraud Investigation Database (FID), System No. 09–70–0527,” at 77760:

“The primary purpose of the system of records is to collect and maintain information to: (1) Identify if a violation(s) of a provision of the Social Security Act (the Act) or a related penal or civil provision of the United States Code (U.S.C.) related to Medicare (Title XVIII), Medicaid (Title XIX), HMO/ Managed Care (Title XX), and Children’s Health Insurance Program (Title XXI) have been committed; (2) determine if HHS has made a proper payment as prescribed under applicable sections of the Act; (3) determine whether these programs have been abused; and (4) coordinate investigations related to Medicare, Medicaid, HMO/Managed Care, and Children’s Health Insurance Program; (5) prevent duplications investigatory

intended disclosure purposes in the ACTS, OPOS and FID notices as for the HITS system notice.²³

CMS states in these notices that it intends to disclose ACTS, HITS, OPOS and FID records to other entities for a variety of other, non-law enforcement purposes. CMS seems mean that any such records cannot be treated as exempt from the Privacy Act, under the proposed Section 5.b.11. CMS has already acknowledged that ACTS, HITS, OPOS and FID records serve many purposes that are not in accord with the requirements for the proposed exemption of being “investigatory materials” or “compiled for law enforcement purposes.”

Some non-law enforcement CMS purposes for these records systems include: agency reimbursement and policy functions; contributing to the accuracy of CMS’s proper payment of Medicare benefits, and/or enabling an agency to administer a Federal health benefits program; quality improvement functions; support for constituent requests made to a Congressional representative; assisting a national accreditation organization; and assisting a state-mandated Protection and Advocacy System that provides legal representation and other advocacy services to beneficiaries. Litigation support for the agency and assisting another agency are other intended disclosure purposes for all these systems is general.

Even if materials in a system are investigatory in nature, the specific purpose for the records may not always fall into a definition of “law enforcement purposes.” Therefore, it is not appropriate for CMS to create a system-wide, categorical exemption for ACTS, HITS, OPUS, and FID records on the basis that they are ubiquitously “investigatory materials” “compiled for law enforcement purposes.”

Loss of Individual Privacy Protections through Regulatory Exemptions

efforts; and (5) provide case file material to the HHS Office of the Inspector General when a case is referred for fraud investigation.”

“Information retrieved from this system of records will also be disclosed to: (1) *Support regulatory, reimbursement, and policy functions performed within the Agency* or by a contractor, consultant, or a CMS grantee; (2) *assist another Federal and/or state agency*, agency of a state government, an agency established by state law, or its fiscal agent; (3) *support litigation involving the Agency related to this system of records*; and (4) combat fraud, waste, and abuse in certain health care programs.”

²³ Ibid on ACTS, “The information retrieved from this system of records will also be disclosed to: (1) *Support regulatory, reimbursement, and policy functions performed within the agency* or by a contractor, consultant or grantee; (2) *assist another Federal or state agency*, an agency established by state law, or its fiscal agent; (3) *assist Quality Improvement Organizations*; (4) *support constituent requests made to a Congressional representative*; (5) *support litigation involving the agency*; (6) *assist a national accreditation organization* that has been granted deeming authority by CMS; (7) *assist a state-mandated Protection and Advocacy System that provides legal representation and other advocacy services to beneficiaries*; and (8) combat fraud and abuse in certain Federally funded health benefits programs.”²³ *(Italics added)*

Among the current Privacy Act protections, from which CMS intends to render the four records systems exempt, include the ability of an individual to: 1) access, copy and request corrections of records where s/he is named; 2) give or withhold consent for records release; 3) to know agency procedures to receive notice when records contain a person's name; and 4) how to exercise individual rights with regard to records. These are substantive rights and can affect a person's livelihood, when federal programs such as Medicare and Medicaid are involved.

Subsection (b) of the Privacy Act requires agencies to have the named individual's written consent prior to disclosing records, with an exception. When agencies make disclosures under (b)(7) "for a civil or criminal law enforcement activity," the named individual's written consent is not required for disclosure and s/he is not entitled to the "accounting" information: "date, nature, and purpose of each disclosure of a record to any person or to another agency," under subsection (c)(3).²⁴ This means that agencies can transmit information to other agencies and persons without the consent of the named individual and without that individual knowing when or what information was transferred, to whom and for what reason. Of course, this level of secrecy is to be reserved only for records disclosure done in the course of *bona fide* "law enforcement activity." CMS' proposed rule sets forth a regulation specifically designed to circumvent a variety of statutory Privacy Act provisions that protect individual rights and detail agency requirements for support of those rights.

CONCLUSION

²⁴ Privacy Act, 5 U.S.C. Section 552a(c)(3), referencing (b)(7):

(c) Accounting of Certain Disclosures

Each agency, with respect to each system of records under its control, shall--

(1) except for disclosures made under subsections (b)(1) or (b)(2) of this section, keep an accurate accounting of--

(A) the date, nature, and purpose of each disclosure of a record to any person or to another agency made under subsection (b) of this section; and

(B) the name and address of the person or agency to whom the disclosure is made;

(2) retain the accounting made under paragraph (1) of this subsection for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made;

(3) except for disclosures made under subsection (b)(7) of this section, make the accounting made under paragraph (1) of this subsection available to the individual named in the record at his request; and. . ."

“(b) Conditions of disclosure

No agency shall disclose any record which is contained in a system of records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record would be—

(7) to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;”

APA strenuously objects to this proposed rule, which is specifically designed to curtail or preclude exercise of many individual rights, such as access to federal records in which the individual is the subject, consent to their release, and the ability to find out when, why and to whom they were released. The proposed rule would also substantially diminish federal agency requirements to notify the public of their Privacy Act rights, to facilitate access, consent and corrections of records, and to follow related due process procedures.

There are many troubling implications to this proposed rule, which substantially contravenes existing law and sound public policy, including CMS' own stringent policies against abridging Privacy Act rights, except for compelling reasons. The proposed exemption would allow disclosure of reputation-damaging records, even if they are erroneous. Losing these Privacy Act protections, especially for accessing and correcting agency records, would prevent physicians from adequately defending themselves from unwarranted complaints and investigations.

CMS has not provided persuasive reasons to support this proposed rule, as is required. CMS has not articulated why these substantive Privacy Act rights and protections should be diminished, what significant public benefits could entail from doing so, or why any perceived benefits outweigh substantial individual Privacy Act rights. Since the 1974 Privacy Act came about, CMS has, presumably, adapted to it in fulfilling its "administrative and program responsibilities," one of which is complying with statutory protections for individuals. This proposed regulation also contravenes CMS' own policy "to protect the privacy of individuals *to the fullest extent possible*" and to exercise authority "*to exempt systems of records only in compelling cases.*"²⁵

APA urges CMS to carefully consider a narrower, more tailored approach to this exemption, in order to conform to its policy of preserving individual Privacy Act rights to the utmost extent, especially with regard to records that are not truly used for law enforcement purposes. The proposed regulation is overly broad and general. It lacks detail that would facilitate interpretation and application. It does not recognize or address differences among types of systems and records, the purpose and use of records within each system at different stages, the different Privacy Act rights and requirements it means to exempt systems from, among other issues.

²⁵ CMS Privacy Act regulations 45 C.F.R. Part 5b:

“§ 5b.3 Policy.

“It is the policy of the Department to protect the privacy of individuals *to the fullest extent possible* while nonetheless permitting the exchange of records required to fulfill the administrative and program responsibilities of the Department, and responsibilities of the Department for disclosing records which the general public is entitled to have under the Freedom of Information Act, 5 U.S.C. 552, and Part 5 of this title.” *(Italics added)*

“§ 5b.11 Exempt systems.

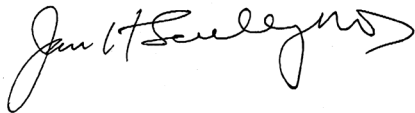
(a) *General policy.* The Act permits certain types of specific systems of records to be exempt from some of its requirements. It is the policy of the Department to exercise authority to exempt systems of records *only in compelling cases.*” *(Italics added)*

CMS should define the terms “investigative materials” and “law enforcement purposes.” CMS should also differentiate among kinds of records within each system that realistically constitute “investigative materials,” as well as agency uses that are not consistent with “law enforcement purposes.” CMS should articulate criteria by which the agency itself and the public can decide which records fall within these definitions and which do not. Enhanced clarity will ensure CMS’ statutory compliance in handling records. A more tailored, detailed regulation may also prevent litigation activity to seek judicial interpretation and to obtain information withheld under the regulatory exemption.

CMS should also adopt regulatory definitions, criteria, guidelines or other means to effectuate a confidentiality promise to an informant and to recognize whether or not one has been effectuated for purposes of agency compliance with Privacy Act subsection (k)(2).

Thank you for allowing APA the opportunity to communicate its concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "James H. Scully Jr.", with a stylized flourish at the end.

James H. Scully Jr., M.D.
Medical Director and C.E.O., American Psychiatric Association

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