June 6, 2011

Terri Postma, M.D.
Acting Director, Performance Based Payment Policy Staff
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1345-P

Dear Dr. Postma:

The Center for Democracy and Technology (CDT), through its Health Privacy Project, promotes comprehensive privacy and security policies to protect health data as information technology is increasingly used to support the exchange of health information. CDT is frequently relied on for sound policy advice regarding the challenges to health privacy and security presented by health information technology (health IT) initiatives. We have testified before Congress four times on the privacy and security issues raised by health IT, and we chair the privacy and security working group of the federal Health IT Policy Committee (called the "Tiger Team").

We have signed onto the comments submitted by the Markle Foundation's Connecting for Health Initiative regarding the "Medicare Shared Savings Program: Accountable Care Organizations" (ACO) proposed rule,[1] but we write separately to comment in more detail on the provisions that require ACOs to provide Medicare beneficiaries with the opportunity to opt-out of having their identifiable Medicare claims information shared with the ACO.

We applaud CMS for establishing this policy and strongly urge that it be retained in the final rule. Building trust in health information exchange requires a comprehensive framework of privacy and security policies that establish clear rules for how health information can be accessed used and disclosed. Such policies should be based on fair information practice principles, and include appropriate oversight and accountability. Most privacy law – including the federal regulations under the Health Insurance Portability and Accountability Act (HIPAA) – is based on fair information practice principles. The ability for patients to have some choice with respect to how their health information is shared is a critical component of fair information practices.

[1] 76 Fed. Reg. 67 (April 7, 2011).

Survey data consistently show that individuals want to have some control over how their health information is shared.[2] CDT has written extensively about the role of consent in protecting health care data, and we understand how in practice, overreliance on consent can result in weak privacy protections because too often individuals are asked to agree to uses and disclosures of their information they do not fully comprehend.[3] The FTC's recent report also highlighted concerns about overreliance on consent in protecting consumer privacy on the Internet.[4]

However, concerns about overreliance consent do not negate its importance as one component of a comprehensive set of policies governing data access, use and disclosure. Building public trust in data sharing through ACOs and other health information exchange infrastructures will require careful attention to the strong desire of individuals to have meaningful choices regarding the sharing of their health data. For example, CDT has recommended providing individuals some choice with respect to having their information exchanged or made available through infrastructures that are new or that diminish the traditional role played by the patient's physician in managing the sharing of medical record data.[5] The Health IT Policy Committee also recommended that the Office of the National Coordinator require meaningful consent before a patient's data is shared in certain exchange infrastructures where the patient's physician is no longer in control over decisions to share information from the medical record.[6] The National Committee on Vital and Health Statistics (NCVHS) has also recommended that individuals have choice with respect to whether or not their health information is part of the Nationwide Health Information Network.[7] FTC also supports providing consumers with simpler and more timely notification and consent with respect to non-routine uses of personal information, such as for targeted marketing.[8]

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[2] In a recent survey conducted by the Markle Foundation, 79% of individuals and 72% of doctors surveyed agreed that patients should be able to make informed choices about how their information is collected, shared and used. Markle Survey on Health in a Networked Life 2011 (January 2011), http://www.markle.org/publications/1461-public-and-doctors-overwhelmingly-agree-health-it-priorities-improve-patient-care; see also "Consumer Engagement in Developing Electronic Health Information Systems," prepared by Westat for the Agency for Healthcare Research and Quality (July 2009) (participants in focus groups tended to support the idea that health care consumers should be asked for their consent before their medical data are stored electronically), http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_888520_0_0_18/09-0081-EF.pdf.

[3] http://www.cdt.org/pr_statement/cdt-paper-rethinking-role-consent-protecting-health-information-privacy.

[4] http://www.ftc.gov/os/2010/12/101201privacyreport.pdf.

[5] Id.

[6] http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy___security_framework/1173

[7] http://www.ncvhs.hhs.gov/060622lt.htm. http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_0_6011_1815_17825_43/http%3B/wci-pubcontent/publish/onc/public_communities/_content/files/hitpc_transmittal_p_s_tt_9_1_10.pdf.

[8] See footnote 3, pages 57-69.

Because identifiable claims data has not routinely been shared by CMS with providers in the past, the sharing of beneficiary identifiable claims data qualifies as a use that, if beneficiaries learned about it after the fact, might surprise them and jeopardize their trust in the ACO program. CMS appropriately recognizes, however, the important role this information can play in enabling ACOs and their participating providers to appropriately manage the care of Medicare beneficiaries. Consequently, we believe CMS made the right choice to provide beneficiaries with the opportunity to opt-out before claims data is shared with an ACO.

We understand that potential ACO participants and other health industry stakeholders are concerned that providing beneficiaries with the right to opt-out of the sharing of their Medicare claims data will significantly hamper their ability to appropriately manage care and control costs and therefore be successful in the Shared Savings Program. We understand these concerns but believe they are overstated. CMS' policy does not limit how ACO participants can share information on beneficiaries from their own records in order to treat beneficiaries and coordinate and manage their care. It applies only to identifiable claims data held by CMS. Thus, any beneficiary who opts out can still have information on his or her care shared with the ACO and among ACO participants. In addition, ACOs will still be able to receive aggregate data on the Medicare beneficiary population, as well as identifying information about the beneficiaries that could be potentially assigned to the ACO.

We also do not believe that many beneficiaries will exercise their right to opt-out, particularly if the ACO's education of beneficiaries encompasses more than mere completion of a form and leverages patients' historic and foundational trust in their health care providers. There does not appear to be a rich literature on the willingness of individuals to agree to the sharing of their health information, but there is growing evidence that individuals generally say yes (or do not object) when they are asked. In the preamble to the proposed rule, CMS cites evidence of high success rates with opt-in for health information exchange in Massachusetts and New York.[9] NCVHS, in recommending that HHS establish policies to provide patients with the right to consent prior to the sharing of sensitive categories of health information, relied on testimony about health care systems in the U.S. and in other countries. They found that "where individuals have the right to put restrictions on disclosure of sensitive health information, people rarely elect to do so, but they strongly value having the right and the ability to do so."[10] In a 2008 survey of parents regarding whether they would permit the use of state newborn blood screening (NBS) samples for research purposes, 76.2% of respondents were willing to permit use of the same for research if the parents permission was obtained first; if permission was not obtained, only 28.2% of the parents were willing to allow the sample to be used for research.[11]

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[9] 76 Fed. Reg. at 19559.

[10] http://www.ncvhs.hhs.gov/080220lt.pdf.

[11] B.A. Tarini et al., "Not without my Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research," Public Health Genomics (DOI: 10.1159/000228724) (Published online July 11, 2009), http://www.cchfreedom.org/pdf/tarini_biobanking%20paper_parent%20attitudes.pdf.

However, given the concerns expressed by a number of provider organizations, we believe it is important for CMS to study the impact of this policy – to keep track of how many beneficiaries opt-out and for what reason, and to study the impact that beneficiary opt-out has on the quality of care delivered by the ACO and its ability to manage costs in the Shared Savings Program. With respect to provider concerns that managing and keeping track of opt-outs would be an undue burden, CMS could consider taking on some of this responsibility, such as by recording beneficiary opt-outs and not disclosing the data of beneficiaries who have opted out (versus relying solely on the ACOs not to request the data).[12]

Although we support the right to opt-out, we do have the following questions and concerns that we hope that CMS will address in the final rule:

ACOs should not rely on pamphlets and forms in educating beneficiaries about ACOs and their right to opt-out

Transparency to beneficiaries about (1) the fact that their health care providers are participating in an ACO, (2) what that means for how their health information will be shared among their health care providers, and (3) that they can opt-out of having their individual Medicare claims data shared with their providers, is critical to building and maintaining beneficiary trust in the program and fulfills a fundamental tenet of fair information practices. In the preamble, CMS notes the importance of ensuring that beneficiaries have meaningful choice with respect to the sharing of their Medicare data and that the choice not be compelled or used to discriminate. We are concerned, however, that CMS is placing too much emphasis on education of beneficiaries through written materials.

It is important that ACOs provide written materials to educate beneficiaries, and in the case of a beneficiary opt-out, it will be important for the ACO to keep written documentation of this choice. We are pleased that CMS is requiring that any ACO educational materials for beneficiaries be approved by CMS,[13] and that CMS also will be producing education materials that can be used by ACOs.[14]

However, beneficiaries will not have meaningful choice if their education consists solely of being provided with pieces of paper to read. It is important that a beneficiary's providers, who are the locus for patient trust in health data sharing, play a role in having discussions with beneficiaries (and, where relevant, their caregivers) in order to ensure full understanding by the beneficiary of what data is being shared, what the benefits are to permitting such data sharing, and what any potential risks may be. (It is not necessary that this conversation take place with the physician – but it should ideally be someone

[12] We have also heard concerns that providing for even opt-out consent in this particular context is one step closer to requiring individual consent prior to any access, use or disclosure of health information. We believe such warnings of dire consequences are without foundation. CMS is proposing a limited opt-out for a specific set of circumstances that carefully balances the desire of individuals for greater control over their health information with the potential impact on health care providers and on CMS.

[13] Proposed § 425.5(d)(4).

[14] 76 Fed. Reg. at 19568.

the beneficiary knows trusts and someone who has full knowledge of the program and can answer questions.) Also, the proposed rule already requires that ACOs have a process in place for "beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values and priorities."[15] Relying primarily on paper materials to educate beneficiaries about their right to opt-out does not qualify as engaging beneficiaries and providing them with an opportunity for input and a discussion that addresses their concerns and respects their needs and values. The final rule should make clear that education about the opt-out must include conversations with beneficiaries (and, where appropriate, their caregivers) – such as during or just after an office visit - to make sure they understand the benefits and potential risks of allowing their Medicare claims data to be shared.

<u>The rules need to be clarified to establish clear limits on how identifiable Medicare claims data can be used</u>

Another important principle in fair information practices is purpose specification and collection and use limitations: specify the purpose for which information is to be collected, and limit your collection and use of the data only to what is needed in order to satisfy that purpose.[16] The proposed rule attempts to set some limitations on the purposes for which identifiable claims data may be used, but the language of the final rule needs some clarification in order to implement fair information practices and effectuate CMS' intent.

In the preamble to the proposed rule, CMS states that ACOs will be required to attest that their use of any requested identifiable claims data will be limited to "Shared Savings Program activities related to one or more of the health care operations" included within the first two paragraphs of the definition of "health care operations" under HIPAA.[17] Under the proposed rule, ACOs are limited to using claims data for the purpose of developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries assigned to the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries."[18] This provision in the rule could be strengthened to state more clearly that ACOs are restricted to using Medicare identifiable claims data for the purpose of coordinating care related to the Shared Savings program.

We also urge CMS to make more clear that the data use agreement (DUA) to be signed by ACOs must restrict ACO use of beneficiary identifiable claims data to managing care *within the ACO*. CMS notes in the preamble that ACOs would be prohibited from sharing claims data with anyone outside the ACO.[19] Unfortunately, the proposed rule provisions

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[15] Proposed § 425.5(d)(15)(ii)(B)(7).
[16] See, for example, ONC's Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information (December 15, 2008), http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy__security_framework/1173; see also the Markle Foundation's Common Framework, http://www.markle.org/health/markle-common-framework/connecting-professionals (P2, Model Privacy Policies and Procedures for Health Information Exchange).
[17] 76 Fed. Reg. at 19558.
[18] Proposed § 425.19(d)(3).
[19] 76 Fed. Reg. at 19557.

regarding the DUA do not expressly incorporate this important restriction from the preamble. The DUA provisions also do not address that use of the identifiable claims data is limited to managing beneficiary care under the Shared Savings Program. The proposed rule states only that the DUA must commit the ACO to complying with the limits of HIPAA and applicable law and prohibit the use of claims data for any prohibited use of identifiable health information.[20] The final rule regarding the provisions required for a DUA should clearly limit ACO data use to managing care under the Shared Savings Program and prohibit ACOs from sharing identifiable claims information with entities outside of the ACO (or if such information is permitted to be shared with contractors, to expressly limit the contractors' use of such information to assisting the ACO in meeting its obligations under the shared savings program and to require the information to be destroyed or returned at the end of the contractual relationship).

The rules should be clear on how ACOs must handle claims data received for beneficiaries who are *not* assigned to the ACO

ACOs are required to limit the use of identifiable claims information to managing health care costs and quality under the Shared Savings Program; however, because beneficiaries are assigned to ACOs retrospectively, ACOs are permitted to request claims information for beneficiaries that could *potentially* be assigned to the ACO. This means that an ACO could continue to receive monthly claims information from Medicare about beneficiaries who are not assigned to the ACO. The proposed rule does not prohibit ACOs from requesting claims data about beneficiaries who do not end up being assigned to the ACO; the proposed rule also does not include provisions regarding what ACOs must do with claims data received on beneficiaries who are not part of the ACO. Instead the proposed rule generally requires claims data to be retained by ACOs for 10 years from the final date of the agreement period.[21]

To effectively implement the limitations on how ACOs can use Medicare identifiable claims data, the final rule should prohibit ACOs from continuing to request claims data on beneficiaries who have not been assigned to the ACO. If there is merit to allowing an ACO to continue to receive identifiable claims information on beneficiaries not assigned to the ACO, this potential broader use of information must be clearly conveyed to beneficiaries as part of the education process. It is also possible that allowing a broader range of purposes for use of this information could have an impact on the number of beneficiaries who choose to opt-out.

The final rule should be strengthened to ensure limitations on use of identifiable claims information are honored and beneficiaries who opt-out are not subject to discrimination

We applaud CMS for making beneficiary notification and provision of the opt-out a condition of participation in the Shared Savings Program, and we applaud the agency's commitment to monitoring this aspect of the program.[22] The proposed rule makes it clear that CMS can terminate an ACO's participation in the program if the ACO or its participants improperly use or disclose claims information received from CMS in violation

[20] Proposed § 425.19(f)
[21] Proposed § 425.16(b).
[22] Proposed §§ 425.12(a) & (e).

of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, or the data use agreement.[23] However, in order to effectively enforce the limitations on use of identifiable claims data, it is critical that the data use agreement be required to include provisions expressly restricting how ACOs can use the data, as noted above.

But CMS needs to do more to ensure that beneficiaries who opt-out are not subject to discrimination. The proposed rule commits CMS to monitoring ACO avoidance of "at-risk beneficiaries,"[24] and authorizes CMS to take action against ACOs who do so.[25] However, the definition of an "at-risk beneficiary" does not include a beneficiary who has opted out.[26] We urge CMS in the final rule to amend the definition of "at risk beneficiary" to include beneficiaries who have opted-out in order to ensure that the ACO and its participants do not discriminate against them.

Typo in Proposed Section 425.19

As a final note, proposed section 425.19(a)(1) appears to be missing a verb. The section currently reads "[t]he ACO does not unnecessary limitations or restrictions on the use or disclosure of individually identifiable health information that it internally compiles from providers and suppliers both within and outside of the ACO." We suggest that in the final rule, it should read "[t]he ACO does not *place* (or *impose*) unnecessary limitations or restrictions…" (emphasis added).

Conclusion

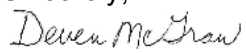
In summary, CDT:

- Applauds CMS for providing beneficiaries with the right to opt-out of having their Medicare identifiable claims information shared with ACOs and urges CMS to retain this in the final rule;
- Requests that CMS improve the Shared Savings Program in the final rule by:
  - Prohibiting ACOs from relying solely on paper and forms to educate beneficiaries about ACOs and their rights to opt-out of having their Medicare identifiable claims data shared;
  - Establishing clear limits on how Medicare identifiable claims data can be used by ACOs;
  - Prohibiting ACOs from requesting Medicare identifiable claims data on beneficiaries not assigned to the ACO; and
  - Expanding the definition of "at risk beneficiary" to include beneficiaries who choose to opt-out.

[23] Proposed § (425.12(a)(15)).
[24] Proposed § 425.12(b).
[25] Proposed § 425.12(b)(2).
[26] See proposed § 425.4.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,



Deven McGraw
Director, Health Privacy Project