

June 6, 2011

Donald Berwick, MD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services, Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington DC 20201

Dear Dr. Berwick:

I am writing on behalf of the Connecticut Health Policy Project (CTHPP) to comment on CMS-1345-P, regarding CMS' proposed rule to implement Section 3022 of the Affordable Care Act -- Medicare Shared Savings Program/Accountable Care Organizations (ACOs). We are specifically commenting on patient privacy provisions of the proposed rule. CTHPP is a nonprofit consumer advocacy and research organization working to expand quality, affordable coverage for every Connecticut state resident.

We want to commend you and your staff for the considerable effort dedicated to developing this proposed rule in a very tight timeframe. We also want to express our strong support for the goals of the rule and ACO development. We share your highest-level goals of improving care for individuals and populations and moderating skyrocketing health costs. We support your focus on care coordination, evaluation, respect for the health care workforce, and patient education. We could not be more pleased with your strong language that an "ACO will put the beneficiary and family at the center of all its activities," a long overdue transformation in how health care is delivered.

However the proposed rule's privacy provisions do not support this patient-centeredness goal. The proposal includes an "opt-out" privacy policy under which consumers' information would be shared across the system unless they refuse. We agree that treating providers should have the information they need, when they need it to provide the most effective treatment possible to every patient, but it is critical that the flow of that information be contingent on each patient's affirmative consent. In fact, the experience of states with opt-in policies for health information exchange is that the vast majority of patients agree and sign a consent form.¹ Nothing is more central to a productive provider-patient relationship than trust and an opt-out policy undermines that trust.

The proposed rule includes an ideal scenario of how the opt-out process could work. "When the beneficiary has a visit with their primary care physician, their physician would inform them at this visit that . . . the ACO would like to be able to request claims information from us [CMS] in order to better coordinate the beneficiary's care. If the beneficiary objects, we propose that the

beneficiary would be given a form stating that they have been informed of their physician's participation in the ACO and explaining how to opt-out of having their personal data shared. The form could include a phone number and/or e-mail address for beneficiaries to call and request that their data not be shared.”ⁱⁱ

Unfortunately this scenario is not realistic in busy primary care practices and we are deeply concerned that this conversation will not happen for many patients. Under the proposed policy it is very possible that many patients will have their most private, sensitive information shared across a system without their knowledge, possibly for years. It would be unfortunate if the first time most of the public becomes aware of health information exchange is after a breach, rather than having the benefits explained at their first primary care visit. The only way to be certain that the conversation you envision takes place is to require each patient's affirmative consent.

The process suggested for patients who wish to opt-out is unrealistic. Increasingly patients in Connecticut and across the US are experiencing difficulty getting appointments with primary care providers and are waiting months to be seen. Expecting patients who finally secure an appointment to ask privacy questions, express to their new provider that they are worried about him/her sharing their data, and ask for a form after a conversation (assuming that one occurs), keep the form and not lose it (assuming that they ever receive it), go home after their visit (possibly stopping at a pharmacy first), and call a phone number or go online to exercise their rights is unlikely to happen with all but the most assertive and sophisticated patients. Realistically, a brochure on a rack or a poster on a bulletin board is all the notice many patients may receive. As advocates, we would be obligated to inform our clients of the risks and this is not the message the advocacy community wants to emphasize about health information exchange.

The proposed rule cites the extraordinary time pressures on primary care providers as one of the reasons not to require consent. Most states with opt-in health information exchange policies report that providers' concerns about administrative burden were exaggerated; many providers initially resistant to opt-in are now champions for the policy. Alternatively the technical issues involved in an opt-out policy could be very burdensome on busy practices. As the proposed rule acknowledges, state and federal laws protect various kinds of sensitive information and require affirmative consent to share. Segregating sensitive data is labor intensive and error prone. The process is not simple – many drugs have multiple uses such as anti-depressants prescribed not for mental illness but to support smoking cessation. Technological options to assist in the task are in their infancy and largely unavailable to small practices. Providers have raised concerns about the quality of care possible if they do not have complete records.ⁱⁱⁱ Even if they are willing to take on the hard work, few providers would be willing to accept liability for ensuring the accuracy of patient data segmentation.

It is widely recognized that the U.S. health care system does a fairly poor job of engaging patients and their families in decisions about and processes of care. There are significant concerns that if patients and the larger public are not confident that they are able to protect and control access to their sensitive health information, it will lead to protective behaviors and serve as a disincentive to accessing care for exactly the patients who need it most.^{iv}

An opt-out policy places consumers who suspect that sensitive information was breached in the difficult position of having rights to redress that they won't know they have even after harm is done. This proposed rule, if adopted, could result in far more sweeping transfer of personal health information than most Americans expect or are aware of, which could undermine public trust in your admirable goals of improving individual and population level health status, coordinating care and shared savings. The proposed opt-out policy undermines momentum toward patient engagement, responsibility and decision-making.

We strongly urge you to reject the opt-out proposed rule and adopt an opt-in rule for patient privacy in ACOs and beyond. We look forward to working with CMS, other government officials and providers to implement ACOs and ensure that they reach their full promise of improving health outcomes and sharing savings.

Sincerely,

A handwritten signature in cursive script that reads "Ellen M. Andrews".

Ellen Andrews, PhD
Executive Director

ⁱ CT Health Information Exchange: Why We Need an Opt-in Privacy Policy, CT Health Policy Project, April 2011, www.cthealthpolicy.org/privacy/20110420_hitect_privacy_memo.pdf

ⁱⁱ CMS-1345-P, Federal Register 76:19560, April 2011.

ⁱⁱⁱ Goldstein M and A Rein, Data Segmentation in Electronic Health Information Exchange: Policy Considerations and Analysis, Office of the National Coordinator for Health IT, September 29, 2010.

^{iv} *Ibid.*