January 14, 2013

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FACA Program Lead
Office of Policy and Planning
Office of the National Coordinator for Health Information Technology
Patriots Plaza III
355 E Street SW
Washington, D.C. 20201

Submitted electronically via www.regulations.gov

RE: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records

Dear Mrs. Robertson:

The undersigned twelve organizations appreciate the opportunity to submit our comments to the Health Information Technology Policy Committee (HITPC) in response to the Request for Comment Regarding the Stage 3 Meaningful Use of Electronic Health Records (EHRs) for the purposes of the Medicare and Medicaid EHR incentive programs. We have come together to support efforts to promote medication adherence in federal, state and private programs to improve care, safety, outcomes and to lower costs.

Medication adherence is when a patient takes their medications according to the specific dosage, time, and frequency prescribed. A breakdown in any one of these elements has the potential to result in unanticipated side effects and complications. Despite this, studies show that:

- Half of all patients do not take their medications as prescribed;
- Twenty percent of all new prescriptions go unfilled;
- Adherence is lowest among patients with chronic illnesses.

Poor medication adherence, or non-adherence, affects patient health by reducing the ability to effectively manage and control chronic diseases. Non-adherent patients are more likely to experience preventable disease progression, increased hospitalizations, doctor and emergency room visits and other problems arising from poor health, which can significantly increase costs. For example:

- 125,000 Americans die annually (89,000 with hypertension) due to poor medication adherence;[i]
- As adherence declines, emergency room visits increase by 17 percent and hospital stays rise 10 percent among patients with diabetes, asthma, or gastric acid disorder;[ii]
- Poor medication adherence results in 33 to 69 percent of medication-related hospital admissions in the United States, at a cost of roughly $100 billion per year;[iii]
- NEHI estimates that total potential savings from adherence and related disease management could be $290 billion annually—13 percent of health spending. [iv]
- 22.5% of prescriptions sent to pharmacies are never even picked up by patients.[v]

The Medicare and Medicaid EHR incentive program holds great promise as a mechanism for advancing the application of medication adherence programs. The HITPC should consider using Stage 3 "meaningful use" (MU) standards to improve patient engagement, strengthen provider tools, such as clinical decision support and eRx, and enhance clinical quality measurement to improve adherence, outcomes, and costs.

General Comments

The expected rapid advancement of new models of care and evolution in health information technology capabilities between now and 2016, when the Stage 3 standards are due to take effect, calls for aggressive MU objectives and a vision which anticipates rather than lags behind technological change. Information technology has the potential to facilitate and advance health delivery system changes, such as care coordination, as well as increase provider and patient engagement. To this end, we urge the HITPC to consider adding a core requirement to the Stage 3 criteria specifically related to facilitating and supporting improved patient medication adherence. This requirement should add new standards and build on the existing adherence related requirements established in Stage 2.

Specifically, the HITPC should consider establishing medication adherence standards and measures or measure sets for providers who treat patients with high cost/high impact chronic conditions related to cardiovascular health, hypertension, diabetes, respiratory illness and mental health. For these patients, the rule should require:

- eRx at 80 percent;
- Measurement of the percentage of medications synchronized to refill concurrently;
- Tracking of prescription fill and refill status at least 80 percent of the time;
- Patient reminders sent to 80 percent of the patients who do not fill or refill their prescriptions as indicated. This information can be provided through the electronic-prescribing network using "fill status notification, whereby pharmacy computer systems send an electronic notification to prescriber EHRs notifying them of the fill status of patients' prescriptions;
- Timely electronic medication reconciliation (on a set interval, ex: performed at least annually, not just on a transition of care, referral, or subjective encounter standard) based on actual drug data linked to the summary of care record, eRx, and active medication list requirements. Other data sources beyond prescriber EHRs should be considered as information sources for medication reconciliation including communication between EHRs and pharmacy computer systems and the electronic prescribing network; and
- Reporting on clinical quality measures for adherence that mirror the Pharmacy Quality Alliance (PQA) developed measures used in Medicare Part D.[vi]

Because successful medication adherence strategies often require a team based approach — typically, a prescriber and a pharmacist — systems must be interoperable across providers. As you know, pharmacists are not eligible for Meaningful Use incentives, so as you build standards related to adherence, we urge you to recognize the importance of bidirectional exchange and that many pharmacists have tools and the information to effectuate medication adherence programs. Often, team based care requires sharing of information that is unrelated to a transition of care or a referral to a provider. We note that the current requirement to transmit a summary of care record is only required on a transition or a referral. Therefore, we suggest requiring that the transition-of-care and referral information be available either as part of

a Health Information Exchange (HIE) or through the Nationwide Health Information Network (NwHIN), in a format that can be sent, received and queried by all healthcare professionals. This format would likely require a transport protocol other than the direct protocol.

For EHR certification standards only, we suggest requiring a capability to integrate consumer mobile application data with a provider's EHR. To achieve this goal, integrated device interoperability will be required and standards should go beyond point-to-point communications.

Additional Comments

SGRP 206 Patient-Specific Education Resources

We support providing educational resources to patients, and recommend adding adherence-specific educational materials as a specific category option within the required resources. Educational materials, such as those provided by the National Consumers League's *Script Your Future*[vii] initiative and the National Council on Patient Information and Education (NCPIE)[viii], are funded by government agencies and seek to provide adherence related information to patients. MU standards that promote patient specific education resources related to adherence should build on these efforts.

SGRP 116 Patient Reminders

We suggest adding the requirements related to patient reminders for patients who are under evaluation for a new medication adherence program. As noted above, prescription fill and refill status should be tracked 80 percent of the time and patient reminders should be sent to 80 percent of the patients who do not fill or refill their prescriptions as indicated. The HITPC should consider tailoring the standards to reflect when a provider's responsibility to issue patient reminders has transitioned to another provider. Such a standard would relieve the transitioning provider from further reporting with respect to patient reminders.

SGRP 207 Secure Electronic Messaging

We support secure messaging as a tool for patients to initiate questions about their medication. Messaging is inexpensive and will foster better communication, access and coordination between providers and patients. To facilitate communication, the response to the patient should be in the same form as the message from the patient.

SGRP 103 eRx

The rule's 50 percent requirement is inadequate in light of the current state of development in eRx and its potential benefits to patients. It is far less costly and more efficient to track and promote medication adherence electronically rather than through paper scripts. We believe that by 2016, eRx technology will reach a sufficient stage of development, and its adoption will be sufficiently widespread, that almost 80 percent of prescriptions should be written and transmitted electronically.

We recognize that regulatory limitations to the electronic prescribing of controlled substances do exist in some states. As a growing number of states do allow this practice, however, we recommend including controlled substance prescriptions in the calculation of permissible prescriptions when allowable by law. We believe this inclusion will stimulate the adoption of electronic prescribing of controlled substances and encourage EHR vendors to

incorporate the necessary requirements into their systems that allow for this practice. As noted above there are many efficiencies seen with eRx and these should not be lost on any certain class of medications.

SGRP 101 Computerized Provider Order Entry

We support CPOE for medication orders and laboratory results. Similar to eRx, however, we believe the threshold, 60 percent of medications ordered using CPOE, is inadequate considering the state of technology and the fact that the measure would apply three years from now to only Stage 3 providers, the most experienced users of EHRs in the Meaningful Use program. In addition, we support drug-drug interaction (DDI) checking for "never" combinations.

SGRP 302 Medication Reconciliation

As noted above, we believe electronic medication reconciliation should be performed on a set interval (ex: at least annually), not just on a transition of care, referral or subjective encounter standard. The medication reconciliation should be based on actual drug data linked to the summary of care record, eRx, pharmacy provided fill and adherence data and active medication list requirements. We applaud the HITPC suggestion that there be an ability to accept data feeds from PBMs, pharmacies and other entities for medication adherence monitoring. Because Medicare Part D plan sponsors are currently required to have the ability to provide patient medication histories to prescribers and dispensers for all Part D eligible patients, we believe this recommendation should be included in Stage 3, rather than a future stage of Meaningful Use.

SGRP 113 Clinical Decision Support

We support expanding the list of required clinical decision support tools and suggest that the HITPC add to the list of interventions a CDS tool for medication management and adherence. This addition would augment the recommendation related to advanced medication-related clinical decision support. We also support the requirement to enable the functionality for drug-drug and drug-allergy interaction checks.

SGRP 106 Maintain Active Medication/Medication Allergy List

We support maintaining up-to-date medication lists, and call on the HITPC to consider requiring measurement of filled and unfilled prescriptions, with information provided from pharmacies, so that providers can engage patients who fail to fill their prescriptions. This is a critical patient safety issue.

ONC10 Prescription Drug Monitoring Programs

ONC requested comment on whether certification criteria could be added for EHR access to prescription drug monitoring programs (PDMPs). We note that the National Council for Prescription Drug Programs (NCPDP) has developed standards for controlled substance reporting that can allow for real time exchange of information between states and, presumably, EHRs.[ix] We recommend that the HITPC and ONC investigate whether the NCPDP standard is appropriate.

Clinical Quality Measures

As discussed above, we suggest adopting the Pharmacy Quality Alliance's (PQA) clinical quality measures currently used in the Medicare Part D star ratings program to measure medication adherence.[x] PQA employs two measures for medication safety and three measures for medication adherence. Because these measures will change over time, we suggest linking the programs in subsequent CMS and ONC rules. This will improve reporting across the programs and provide data from which researchers can draw additional insights.

Conclusion

Thank you for requesting comments on the Health Information Technology Policy Committee's recommendations. We appreciate the opportunity to comment and look forward to working with you to improve Meaningful Use standards that advance medication adherence interventions. If you have any questions or would like to discuss further, please do not hesitate to reach out to Joel White, Executive Director, the Council for Affordable Health Coverage, at joel.white@cahc.net or (202) 266-2630.

Sincerely,

AARDEX Group
CVS Caremark
CAHC Medication Adherence Policy Alliance
LTCPCMS
Merck & Co.
Mirixa
MWV Healthcare
National Association of Chain Drug Stores
National Consumers League
National Council for Community Behavioral Healthcare
National Council on Patient Information and Education
Pharmacy Quality Alliance

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[i] McCarthy, R., "The price you pay for the drug not taken." *Bus Health*. 1998;16:27-28,30,32-33.
[ii] Goldman, D., "Pharmacy Benefits and the Use of Drugs by the Chronically Ill.", *Journal of the American Medical Association*, 19 May 2004.
[iii] Osterberg L., Blaschke T., "Adherence to medication." *N Engl J Med*, 2005;353(5):487-497.
[iv] NEHI Research Brief, "Thinking Outside the Pillbox: A System-wide approach to Improving Patient Medication Adherence for Chronic Disease." *NEHI,* 2009.
[v] Fischer MA, Stedman MR, Lii J, et al. "Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions." *J Gen Intern Med*. 2010 April; 25(4): 284–290.
[vi] For more information, visit http://pqaalliance.org/measures/default.asp.
[vii] For more information, visit scriptyourfuture.org.
[viii] For more information, visit www.talkaboutrx.org; *See also, "*Your Medicine: Be Smart. Be Safe", available at, http://www.talkaboutrx.org/educational_resources.jsp.
[ix] The NCPDP Telecommunication Standard is available by contacting NCPDP through www.ncpdp.org.
[x] For more information, visit http://pqaalliance.org/measures/default.asp.