Prescriptions for a Healthy America

"A Partnership for Advancing Medication Adherence"

May 29, 2015

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Submitted electronically via: www.regulations.gov

RE: RIN 0991-AB93; 2015 Edition Health Information Technology Certification Criteria, 2015 Edition Base Electronic Health Record Definition, and ONC Health IT Certification Program Modifications

Dear Dr. DeSalvo:

Prescriptions for a Health America (P4HA; www.adhereforhealth.org) is pleased to submit comments on the 2015 Edition HIT Certification Criteria, Base EHR Definition, and ONC HIT Certification Program Modifications Proposed Rule. P4HA is a multi-stakeholder alliance representing patients, consumers, providers, pharmacies, pharmaceutical manufacturers and employers. We joined together to raise awareness on the growing challenges posed by medication non-adherence, and to advance public policy solutions that will help reduce health care costs and improve the lives of patients across the nation through medication adherence interventions.

Medication adherence occurs when a patient takes their medications as prescribed, which includes taking them according to the specific dosage, time, and frequency prescribed. A breakdown in any one of those 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; and
- Adherence is lowest among patients with chronic illnesses. [1,2]

[1] Lee J, Grace K, Taylor J. Effect of a primary care program on medication adherence, persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. *JAMA*. 2006: 296(21) 2563-
[2] Sabate E. editor. Adherence to long-term therapies: evidence for action. World Health Organization. Geneva, Switzerland; 2003.

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 additional problems arising from poor health, which can significantly increase costs. For example:

- At least 125,000 Americans die annually due to poor medication adherence;
- As adherence declines, emergency room visits increase by 17 percent and hospital stays rise 10 percent; and
- 33 to 69 percent of medication-related hospital admissions in the United States are a result of nonadherence, costing roughly $100 billion per year.[3,4]

The Medicare and Medicaid EHR incentive program (MU) holds great promise as a tool to advance medication adherence strategies. Various functionalities and measures associated with MU can assist both providers and patients in improving medication adherence. We commend the Department for their focus on the various aspects of Meaningful Use that can be applied to reducing medication non-adherence. We believe doing so will help to address the significant defects produced by this avoidable behavior, and assist in improving health outcomes and lowering health costs in the United States.

Our comments on the proposed rule are outlined below.

Electronic Prescribing

P4HA supports ONC's proposal that health IT modules be required to receive and respond to additional NCPDP SCRIPT Standard Implementation Guide Version 10.6 transactions or segments, specifically Fill Status and Medication History. P4HA previously commented on the importance of including medication history and fill status as part of EHR functionality in the ONC's Voluntary 2015 Edition EHR Certification Criteria proposed rule in April 2014.[5] We commend ONC for proposing to adopt these transactions.

Medication History is necessary for obtaining an accurate picture of all of the prescription medications a patient is currently prescribed; it is also key for assisting prescribers in avoiding potential drug-drug interactions. Information on the Fill Status of a patient's medications can help to further strengthen existing tools- like medication history- while also ensuring patient adherence to medications is assessed in the physician office. For the information generated and gathered when a patient fills, refills or fails to fill a prescription to be valuable, data flow must be bi-directional. The Fill Status capability of the NCPDP

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[3] IMS Institute for Healthcare Informatics, "Avoidable Costs in US Healthcare: the $200 Billion Opportunity from Using Medicines More Responsibly," June 2013, http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=12531cf4cc75f310VgnVCM10000076192ca2RCRD&vgnextfmt=default

[4] Viswanathan M, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review, *ANN INTERN MED.* 2012;157(11):785-795.

[5] http://www.regulations.gov/#!documentDetail;D=HHS-OS-2014-0003-0044

SCRIPT Standard v10.6 achieves this goal. Furthermore, we support the proposal to require e-prescription directions for medication use be transmitted and codified in a structured format. We commend ONC for recognizing these functionalities in its 2015 edition health IT certification criteria.

Drug Formulary and Preferred Drug List Checks

Physicians that have real-time access to information related to a patient's insurance coverage – including drug formularies – can meaningfully engage with patients regarding medication options. As they prescribe a medication for their patient, physicians and other prescribers may not know whether a particular drug is covered by the patient's insurance. If it is covered, they may be unaware of the tier and cost-sharing requirements, which can lead to primary non-adherence if the patient is unprepared and/or unable to pay when picking up the prescription or reconciling bills if filled by mail order. Including the drug formulary functionality within an EHR at the point of prescription can therefore help facilitate a conversation between the prescriber and patient on the importance of medication adherence.

To this end, P4HA supports ONC's dual-goal that the Health IT Module must (1) automatically check whether a drug formulary exists for a given patient and medication and (2) receive and incorporate a formulary and benefit file according to the NCPDP Formulary and Benefit Standard V3.0. Furthermore, we support ONC's recommendation that the Health IT Module be capable of indicating the last update of a drug formulary. Up-to-date formulary information is clearly more useful than out-of-date information and it would be beneficial to prescribers to know if they are using current formulary information.

We also note that CMS proposes to require qualified health plans (QHPs) in the Federally-Facilitated Marketplaces to make formulary and benefit information available in a machine-readable format.[6] In addition, Part D plans are required to provide formulary data in a codified form for display on the Medicare Plan Finder. ONC should work with CMS to ensure that technology developers are aware of the availability of machine readable formulary content for purposes of improving the formulary and benefit information available to prescribers in electronic health records (EHRs). P4HA believes that technology developers should also be encouraged through the MU certification criteria to improve formulary and benefit checks in EHRs via existing information and current requirements of other federal health programs.

Conclusion

Thank you for requesting comments on the 2015 Edition HIT Certification Criteria, EHR Definition, and HIT Certification Program Modifications Proposed Rule. We appreciate the opportunity to comment and look forward to working with you to continue improving the EHR functionality that will advance medication adherence interventions. We welcome the

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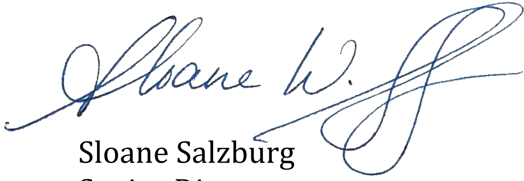
[6] Federal Register Volume 80, Number 60 (Monday, March 30, 2015). Pages 16687-16688. FR Doc No: 2015-07089.

chance to address any questions ONC might have regarding our remarks or to provide any additional input as these proposals evolve.

Sincerely,



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