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IDSA
Infectious Diseases Society of America

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Submitted via: http://www.regulations.gov

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 [CMS-3310-P]

Dear Mr. Slavitt:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for the opportunity to comment on the proposed regulations relating to Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3.

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), and multi-drug resistant Gram-negative bacteria such as Acinetobacter baumannii, Klebsiella pneumoniae, and Pseudomonas aeruginosa, including some containing the New Delhi metallo-beta-lactamase (NDM) enzymes that makes them resistant to a broad range of antibacterial drugs, as well as emerging infections such as Middle East Respiratory Syndrome coronavirus (MERS-CoV) and Ebola.

Effective use of health information technology (HIT) and electronic health records (EHR) is essential for improving patient care and public health in the 21st century. As infectious diseases specialists, we recognize the promise of HIT and EHRs to help prevent, treat, monitor, and control infectious diseases in both the healthcare delivery setting and the community. Successful implementation of the Meaningful Use (MU) program will require a sustained commitment, including consideration of financial support for practitioners, hospitals and healthcare systems, and strong leadership from the federal government. We offer our support and assistance to the CMS during the implementation phase.

IDSA members are committed to improving the quality and safety of patient care in a manner that meaningfully applies the advanced use of certified EHR technology (CEHRT) to promote health information exchange and improved outcomes for patients. We recognize that the changes as set forth in these proposed rules intend to reasonably advance the adoption of EHR technology across the healthcare

system. Below we submit our comments with hopes of improving the evolution of the EHR Incentive Program by providing our perspective on the implications of the proposed changes.

This proposed rule aims to level-set all providers, by the beginning of 2018, to report on the same definition of MU at the Stage 3 level regardless of their prior participation, moving all participants in the EHR Incentive Programs to a single stage of MU in 2018. As stated in the rule, this is in response to stakeholder input regarding the complexity of the program, the success of certain measures, which are part of MU program to date, and the need to set a long-term, sustainable foundation based on a consolidated set of key advanced use objectives for the Medicare and Medicaid EHR Incentive Programs. In this rule, there are proposed changes to the EHR reporting period, timelines, and structure of the Medicare and Medicaid EHR Incentive Programs intended to provide a flexible, clear framework to reduce provider burden, streamline reporting, and ensure future sustainability of the Incentive Programs.

IDSA maintains its belief in the value of EHRs and their role in quality improvement if used in a meaningful manner to improve patient safety and the efficiency of clinical care. A significant change that CMS has proposed for Stage 3 is the creation of a single, uniform definition of MU that all providers would be required to adhere to by 2018, regardless of their prior participation in the program. While we appreciate the intent to streamline the program's requirements and to minimize administrative complexity, our general concern with the proposed changes in this rule that directly impact our members is that the rule dramatically raises the bar for eligible providers (EPs) to achieve MU in a "one-size-fits-all" approach, while imposing an "all-or-nothing" approach to successful participation. In other words, the program fails to recognize the variability in the application of health information technology across specialty care and penalizes best efforts to adopt technology that still result in partial achievement towards objectives. In addition, we have concerns with the insufficiency of current certification standards that do not achieve true interoperability and, until this is addressed, our members will be limited in their ability to use EHRs for data exchange that results in quality improvement. We encourage CMS to offer a wider assortment of menu objectives so that EPs have the flexibility to choose those that are most relevant to their practices/patient populations and to recognize best efforts that may fall short of achievement of full program compliance.

Through this rule, CMS proposes to eliminate the 90-day reporting period for first year participants and requires that EPs attest to MU for a full year, beginning in 2017. Traditionally, all new participants to the EHR/MU program have been given the option to report for a 90-day period to allow them to get acclimated to the program, and this exception should be extended into the future. Those who are new to the program, even in 2018, should not be held to the same bar as those who have been participating for multiple years. As well, there are limitations to existing hardship exemptions to allow for recognition of the difficulty that EPs, who have previously adopted certified EHRs, now face in trying to comply with the 2015 edition by 2018. As EPs demonstrate genuine intent to comply, investing significant resources in updating existing EHRs or adopting new ones, they face the risk of not achieving 100% of the objectives, which will bring financial penalties. We urge CMS to adopt a mechanism that incrementally recognizes genuine efforts to achieve MU, rather than penalizing EPs for not satisfying every single requirement.

Finally, this program was intended to follow a staged process that gradually encouraged providers to work towards more advanced uses of EHR technology. This proposed rule seems to move further away from the original goals of the program.

Comments Related to Specific Stage 3 Proposals

Objective 1: Protect Patient Health Information
IDSA recognizes the importance of safeguarding electronic health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards. This measure requires that a security risk analysis be performed according to regulations to ensure the security of the data stored in the EHR, to include all applicable updates and identified corrective action. Whereas we do not object to the measure, we are concerned about the burden it places on EPs in small practices who may not have the staff support to adequately perform and address security risks.

Objective 2: Electronic Prescribing
Under this objective, CMS is proposing to raise the requirement threshold from 50% to 80% of all permissible prescriptions written by the EP that are queried for a drug formulary and transmitted via the EHR. IDSA asks CMS to consider setting a smaller increase from the previous threshold to reflect a more gradual transition and consider that an 80% threshold would be quite challenging for first-time participants. We appreciate CMS' exemption of EPs who write fewer than 100 permissible prescriptions as this may apply to many of our members.

Objective 3, Measures 1: Clinical Decision Support (CDS)
Measure 1 requires that the EP implement five clinical decision support interventions related to four or more Clinical Quality Measures (CQMs). Absent four CQMs related to an EP's scope of practice or patient population, the CDS intervention must be related to a high-priority health condition. The challenge that we see in our members complying with this measure is that EPs rely on EHR vendors to deliver more sophisticated CDS embedded in their technology. Much of the existing CDS exists at a fairly basic clinical level and much of it is not specific to infectious diseases, except for some HIV-related CQMs. In order to achieve this objective in a meaningful way that relates more broadly to the care that ID specialists provide, EHR vendors will need to deliver more diversified, more relevant and more sophisticated CDS tools. In the event that they do so, it will likely require significant additional investment to implement.

Objective 5, Measure 1: Patient Electronic Access to Health Information
Measure 1 calls for providing more than 80% of all unique patients seen by the EP with online access to view, download, and transmit health information within 24-hours of its availability to the provider or provide access via an Office of the National Coordinator for Health Information Technology (ONC)-certified application-program interface (API) with interconnectivity for third-party applications or devices to enable patient access to the information. IDSA believes that allowing patients access to information relevant to the care they receive is important so long as the onus of accessing the information is placed on the patient, and not the EP. We are supportive of measure 1 because it does not require the patient to take action in order for the EP to achieve the objective. However, we believe that the reduction in the time period in which the EP must make the information available to the patient, from 4-days to 24-hours, is particularly

concerning for our members, many of whom see patients at several facilities and face existing challenges in collecting information from disparate sources. We ask that CMS consider these issues when finalizing the proposed change.

Objective 6, Measure 1, 2, & 3: Coordination of Care through Patient Engagement
Measure 1 would require that more than 25% of all unique patients seen by the EP actively engage with the EHR. This could be demonstrated by the patients viewing, downloading or transmitting to a third-party their information or by accessing their health information via the use of an ONC-certified API with interconnectivity to third-party applications of devices (similar to Objective 5, measure 1). We are concerned with this measure, as it requires action on the part of the patient in order for the EP to achieve the measure objective. Moreover, we are concerned that the threshold has increased from 5% of patients seen during the reporting period to 25%

Measure 2 requires that a secure message be sent using the electronic messaging function of CEHRT to more than 35% of the unique patients seen by the EP during the reporting period. This 35% threshold is a dramatic increase from the 5% previously required.

Measure 3 calls for the incorporation of patient-generated health data or data from a non-clinical setting into the CEHRT for more than 15% of all unique patients seen by the EP. Here again, we express concern for a measure that requires patient action in order for the EP to achieve the objective. We also request that CMS more clearly define what it would accept as "non-clinical setting data."

Objective 8, Measure 1: Immunization Registry Reporting
IDSA strongly supports continued promotion of the use of State Immunization Information Systems (IIS or "registries") across the lifespan. Every year, tens of thousands of adults die and many more are hospitalized due to diseases that could have been prevented by vaccination.[1] Although >90% of young children have received the individual vaccines recommended for them, coverage for adult vaccines can range from 26% to 65% depending on the vaccine and target population—well below the Healthy People 2020 targets.[2] State Immunization Information Systems (IIS or "registries") can be a powerful tool for states to manage pediatric, adolescent, and adult vaccine schedules, and to help both healthcare providers and patients identify immunization gaps and avoid redundant vaccinations. Although IIS use has been shown to help increase immunization rates in children,[3] adolescent and adult participation in IIS is too low to effectively boost vaccine uptake in the same way. In 2012, only 24.5% of adults ≥19 years participated in an IIS, compared with 86.0% for children.[4] In a recent survey of provider perspectives on adult immunization, only 8% of general internists and 36% of family medicine practitioners reported recording adult immunization information in a state or regional IIS.[5]

[1] National Vaccine Advisory Council (NVAC). "A Pathway to Leadership for Adult Immunization: Recommendations of the National Vaccine Advisory Committee." Public Health Reports. Jan-Feb 2012; 127(Suppl 1)1.
[2] *Available at* http://www.healthypeople.gov/2020/default.aspx.
[3] Task Force for Community Preventive Services. Increasing appropriate vaccination: Immunization information systems (2010).
[4] U.S. Centers for Disease Control and Prevention. Progress in immunization information systems – United States, 2012. Morbidity and Mortality Weekly Report. Vol. 62 No. 49 (December 13, 2013).
[5] Hurley, L. et al. U.S. physicians' perspective of adult vaccine delivery. Ann Intern Med. 2014;160:161-170.

We therefore support the transition from the "Ongoing Submission" to the "Active Engagement" requirement and we are pleased that bidirectional data exchange is required to satisfy this measure. However, we are concerned that the proposed rule no longer includes immunization registry reporting as a core objective for EPs. Including registry reporting as a core objective for MU Stages 1 & 2 helped to significantly improve immunization data reporting, and we fear that this progress may not be sustained if it is dropped.

More broadly, we stress that more is needed to ensure that states can successfully onboard eligible entities into the IIS. In a 2014 9-state survey, conducted as part of a pilot project led by IDSA in partnership with the National Adult and Influenza Immunization Summit (NAIIS), states reported bottlenecks that delayed MU implementation, including provider decisions not to transition from MU Stage 1 to 2 because of technological and financial barriers, lack of state staff and funding for a dedicated IIS MU team (most states relied on department-wide MU team and external IT departments and only one state had dedicated full-time staff for MU), and EHR vendor delays.[6] Moreover, it was clear that states prioritized providers of pediatric immunizations in MU implementation because those providers administered a higher volume of immunizations, were more likely to be prepared to dedicate resources to complete the project, and had an established record of reporting to the IIS.

In the short term, much can be done to increase the profile of IIS as a tool to boost adult vaccine coverage. IDSA supports strategies to expedite EHR connectivity and ease of data transfer between IIS platforms, state development of web-based patient access portals, and education and awareness initiatives to increase provider and patient knowledge of the benefits of IIS use. These strategies should also include non-traditional or community providers (e.g., pharmacies). By improving both providers' and patients' ability to document and access immunizations administered and needed, more adults will have the opportunity to maximally reduce their risk of vaccine preventable diseases through vaccination. Finally, it is important that states have sufficient funding. IDSA urges the CMS to consider the challenges facing IIS adoption when finalizing and implementing MU Stage 3.

Objective 8 Measure 3: Case Reporting

IDSA welcomes the addition of the case reporting measure. We believe such a measure will help public health agencies detect and respond to outbreaks of concern. However, we stress that additional measures are necessary to ensure high quality data and sufficient funding for public health agencies to accept data transmissions.

A well-designed case reporting program would ensure that a report is only generated for a result that clearly represents a new episode of a disease of interest (e.g., a new positive HIV antibody or new sputum culture for tuberculosis). Alternatively, if a system sets up a provider diagnosis of a disease to get sent as a new case, errors could occur when working diagnoses get reported as confirmed cases. We therefore support ongoing federal efforts to support consistent reporting of high-quality data.

[6] National Adult and Influenza Immunization Summit. Using Immunization Information Systems to Increase Adult Vaccine Uptake: A Report from the National Adult and Influenza Immunization Summit. Unpublished Manuscript. June 2014.

We are also concerned that the third allowable exclusion for this measure, for eligible entities that "operate in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period" segregates clinical and public health needs at what is, in essence, a crucial clinical-public health interface. Failure to fund public health information systems that link with clinical EHRs will keep this MU Stage 3 goal from realization as there is no current funding stream to insure that the needed interfaces can be created. Similar federal regulations promulgated in the past have required facilities/providers to report to public health agencies at the state or local level, but were not matched by funding to build capacity in those public health agencies to receive, collate, interpret, report, act on and publicize as appropriate those reported events.

IDSA appreciates the opportunity to comment on these proposed rules. We look forward to working with the CMS to fulfill the promise of HIT to advance patient care and public health. If you have any questions about these comments, please contact Andrés Rodríguez, IDSA Director of Practice & Payment Policy at arodriguez@idsociety.org / 703-299-5146 or John Billington, IDSA Director of Health Policy, at jbillington@idsociety.org / 703-299-0015.

Sincerely,

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