



**American Hospital
Association®**

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

March 22, 2016

Patrick Conway, M.D.
Acting Principal Deputy Administrator
Centers for Medicare & Medicaid Services
Mail Stop C5-25-25
7500 Security Boulevard
Baltimore, MD 21244

Re: A Flexible Approach to Meaningful Use

Dear Dr. Conway:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) encourages the Centers for Medicare & Medicaid Services (CMS) to consider eliminating its “all-or-nothing approach” to meaningful use of electronic health records (EHRs). Under this approach, failure to meet any one of the requirements under the Medicare and Medicaid EHR Incentive Programs has meant a provider would not receive an incentive payment; more recently, it has meant a provider would be penalized. The AHA has recommended against this misguided policy since the inception of the programs. Given the complexity and level of difficulty in meeting all of the meaningful use criteria, the all-or-nothing approach – in which failure to meet any individual part of an objective, or missing a threshold by a small amount, leads to overall failure in meeting meaningful use – is overly burdensome. It is also unfair to providers that make good faith efforts to comply, may actually comply with a large percentage of the requirements, expend significant resources and funds in doing so, but still fall short.

Providers are committed to utilizing information technology (IT) as part of a foundation for care improvements, patient engagement and new models of care. The AHA appreciates the modifications CMS made to the EHR Incentive Program in 2014 and 2015. Your recognition of the need for flexibility in program requirements supported providers in their ongoing work to adopt and use these tools. We welcome your willingness to continue to work together to increase the odds of provider success. To that end, the AHA has consistently urged CMS to allow providers to implement a percentage or limited number of the meaningful use objectives and offer providers greater flexibility in choosing which requirements to implement.¹ Most recently,

¹ The AHA has submitted at least eight comment letters to CMS, beginning in 2010, in which we made this request. We would be happy to provide copies of those comment letters at your request.



in December 2015, we “urge[d] CMS to adopt an alternate approach that advances widespread health IT adoption by all [providers] and sets requirements that are achievable and practical. Specifically, **the AHA recommends that [providers] that attest to meeting 70 percent of the meaningful use requirements be designated as having met meaningful use.**”²

In declining to provide greater flexibility, CMS has emphasized that the statute requires the agency to impose more stringent measures of meaningful use to improve the use of EHRs and health care quality over time.³ While this is correct, it does not preclude a more flexible approach. **Rather, CMS can meet its obligation to impose more stringent measures to achieve the statutory goals over time without taking an all-or-nothing approach to the number of objectives that must be satisfied in order to meet program requirements.**

CMS IS AUTHORIZED TO TAKE A MORE FLEXIBLE APPROACH THAN “ALL-OR-NOTHING”

CMS has provided several reasons for not adopting an alternate approach to “all-or-nothing.” While CMS has pointed to various statutory provisions to support its decision, the agency has not actually stated that it lacks the legal authority to accommodate the AHA’s request. In recent conversations with the AHA, however, the agency, for the first time, said that it does not believe it has the statutory authority to adopt our recommended approach. For the reasons outlined below, **we believe that CMS possesses the authority to eliminate the all-or-nothing approach to meaningful use and that the agency should do so by allowing providers that attest to meeting 70 percent of the meaningful use requirements to be designated as meaningful users.**

THE STATUTE DOES NOT REQUIRE AN ALL-OR-NOTHING APPROACH

An analysis of CMS’s authority to permit a more flexible approach to meeting meaningful use starts with the language of the statute. Section 1886(n)(3) of the Social Security Act (SSA) defines a “meaningful EHR user.” An eligible hospital⁴ is a meaningful user if it meets three criteria:

(i) **MEANINGFUL USE OF CERTIFIED EHR [SIC] TECHNOLOGY.**—The eligible hospital demonstrates **to the satisfaction of [CMS]** . . . that . . . the hospital is using certified EHR technology in a meaningful manner.

(ii) **INFORMATION EXCHANGE.**—The eligible hospital demonstrates **to the satisfaction of [CMS]** . . . that . . . such certified EHR technology is connected in a manner that provides . . . for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

² Letter from Thomas P. Nickels, AHA, to Andrew M. Slavitt, Acting Administrator, CMS (Dec. 11, 2015) (emphasis in original).

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886(d). Eligible hospital also includes critical access hospitals and Medicare Advantage-affiliated hospitals. See https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/eligible_hospital_information.html.

(iii) REPORTING ON MEASURES USING EHR.— . . . [U]sing such certified EHR technology, the eligible hospital submits information for such period, **in a form and manner specified by [CMS]**, on such clinical quality measures and such other measures **as selected by [CMS]**

SSA § 1886(n)(3) (emphasis added).

As the highlighted language shows, Congress gave CMS exceedingly broad discretion to determine whether a hospital is a meaningful EHR user. And that broad discretion is not found in only one of the criteria defining a meaningful user, but rather it extends to *each* of the three. At the same time, there is nothing in any of the three criteria that requires CMS to adopt an all-or-nothing approach to meaningful use. **It is clear that the statutory definition of meaningful EHR user permits CMS to employ the more flexible approach advocated by the AHA and others.**

CMS HAS OFFERED POLICY, NOT LEGAL, REASONS FOR ITS ALL-OR-NOTHING APPROACH

As noted above, CMS said that “stakeholder associations and providers have requested changes to the number of objectives and measures that providers must meet to demonstrate meaningful use of certified EHR technology. CMS adds that it “reviewed these recommendations and declined to follow this course for a number of reasons” (80 Fed. Reg. 16,740. March 30, 2015). But we do not believe CMS’s reasons are, in fact, a legal bar to the flexibility the AHA seeks. Instead, the reasons either reflect a clear policy choice or misconstrue the requirements of the statute. We discuss each below in turn.

1. CMS’s first contention: The statute requires more stringent measures of meaningful use to improve quality over time.

CMS explains that “the statute specifically requires [CMS] to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use” (*Id.*). The AHA does not disagree. But requiring more stringent measures of meaningful use does not similarly require the all-or-nothing approach adopted by CMS.

The statute states that CMS “shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph” (SSA § 1886(n)(3)). As an initial matter, we note that this language is not part of the definition of meaningful EHR user; instead, it is directed to CMS. Moreover, all that this language requires is that CMS *seek* to improve the use of EHRs and health care quality *over time* by requiring more stringent measures. In order to meet this requirement, CMS need only work toward such improvements, not immediately achieve them. Similarly, “seek[ing] to improve the use of electronic health records and health care quality over time” does not require a constant upward trajectory; rather, there might be relatively short periods when measures might plateau or be less stringent. After all, the statute does not say that CMS must seek to improve the use of EHRs and health care quality over time by *consistently* requiring more stringent measures. Additionally, the statute’s reference to more stringent measures cannot mean that a hospital would have to meet every measure ever adopted by CMS; otherwise, CMS would not be able to retire any measures. Yet we know that the agency “eliminate[s] measures that are . . . redundant,

duplicative, and ‘topped out’” (80 Fed. Reg. 16,732, 16741. March 30, 2015). **Therefore, as long as more stringent measures are required over time, CMS has met its duty.**

CMS would be able to satisfy this statutory duty under the more flexible approach suggested by the AHA. That is, under the more flexible approach, the agency would seek to improve the use of EHRs and health quality by requiring more stringent measures over time, even if, at certain points in time, hospitals did not have to meet some requirements. Thus, CMS could conclude that a hospital that attests to meeting 70 percent of the meaningful use requirements is a meaningful user.

2. CMS’s second contention: Certain objects and measures capture policies specifically required by statute.

CMS also suggests it is unable to adopt a flexible approach to meaningful use because certain objectives and measures capture policies required by the statute. For example, CMS states: “Specific to the health information exchange, the statute requires certified EHR technology connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination” (*Id*). But these statutory requirements could be met under the flexible approach recommended by the AHA.

Congress explicitly stated that it is up to CMS to determine whether it is satisfied that the statutory requirement has been met: “The eligible hospital demonstrates **to the satisfaction of [CMS]** . . . that . . . such certified EHR technology is connected in a manner that provides . . . for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination” (SSA § 1886(n)(3)(ii). Emphasis added.). **In light of the broad discretion Congress granted CMS, the agency could readily conclude that it is satisfied that the statutory requirement has been met under less than an all-or-nothing approach. That is, not every requirement would have to be met for CMS to find itself “satisfied” that the “certified EHR technology is connected in a manner that provides . . . for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.”**

3. CMS’s third contention: Use of a “qualified EHR” must meet all the requirements in order to satisfy the objectives of the law.

CMS’s third reason for not adopting a flexible approach to meaningful use is that providers must use a “qualified EHR” that has the capacity to do certain things and “the objectives that address these requirements . . . would be undermined if providers were allowed to fail to meet these objectives and still be considered meaningful EHR users” (80 Fed. Reg. 16,732, 16,741. March 30, 2015). CMS does not elaborate on the reasons why it reaches this conclusion. The agency does not say that the statute makes it impermissible for providers to fail to meet these objectives and still be meaningful users. The statute does not address the objectives that CMS considers “foundational goals of the program, which would be undermined if providers were allowed to fail to meet these objectives and still be” meaningful users (*Id*). Thus, CMS’s third reason for holding to the all-or-nothing approach is not rooted in the statute.

Patrick Conway, M.D.

March 22, 2016

Page 5 of 5

4. CMS's fourth contention: The flexible approach would not reduce burden.

The fourth reason CMS proffered for rejecting a flexible approach to meaningful use is that it would not accomplish the providers' stated goal of reducing reporting burden. While the AHA respectfully disagrees with this conclusion, it seems clear that CMS's conclusion is not based on the statute and, therefore, would not present a bar to the adoption of a flexible approach.

* * *

According to our analysis, we strongly believe that CMS is not legally required to maintain its all-or-nothing approach to meaningful use. Rather, we believe that the agency possesses ample legal authority to adopt a more flexible approach, such as the one recently proposed by the AHA. Under that approach, a hospital that attests to meeting 70 percent of the meaningful use requirements would be considered a meaningful user. This flexibility would support providers who have implemented IT functionality but may not have optimized each function sufficiently to meet the full set of requirements in the EHR Incentive Program in order to avoid a payment adjustment.

Should you have any questions concerning this letter, please contact me or Diane Jones, senior associate director of policy, at (202) 626-2305 or djones@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

cc: Janice L Hoffman, Associate General Counsel, U.S. Department of Health and Human Services

Kate Goodrich, M.D., Director, Center for Clinical Standards and Quality, Center for Medicare and Medicaid Services