The Joint Commission

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Dear Ms. Verma:

The Joint Commission appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS) proposed rule governing the *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal year 2018 Rates; Quality reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices*.

Founded in 1951, The Joint Commission seeks to continuously improve health care for the public in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. An independent, not for-profit organization, The Joint Commission accredits and certifies more than 21,000 health care organizations and programs in the United States. The Joint Commission evaluates health care organizations across the continuum of care, including most of the Nation's hospitals. In addition, our programs encompass clinical laboratories, ambulatory care and office based surgery facilities, behavioral health care, home care, hospice, and long-term care organizations. Joint Commission accreditation and certification are recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting state-of-the-art performance standards. Although accreditation is voluntary, a variety of Federal and state government regulatory bodies, including CMS, recognize and rely upon The Joint Commission's decisions and findings for both either Medicare or licensure purposes.

Overarching Comments

The Joint Commission welcomes the opportunity to respond to many areas in the proposed rule, especially to the Request for Information (RFI) on ways to improve quality throughout the health care system while reducing regulatory burden and costs. This RFI is an important vehicle on the journey to permit the private sector to apply its expertise and to excel in achieving the goal of high quality, safe health care. At the same time, The Joint Commission wishes to express its deep concern over, and opposition to, the provision to require the release of private sector accreditation reports and providers' plans of correction. This provision will directly work against that same quest for high quality, safe care and will countervail the achievements in quality and safety that have been realized

to date, as well as vastly diminish expected future gains. Let us be very clear, The Joint Commission strongly supports the provision of reliable and valid data on the quality of health care to the public and was the first organization in the United States to develop and publish nationally standardized data on quality for thousands of hospitals. That program continues to this day, some 15 years after its inception. We believe, however, that the publication of information about quality must be accomplished in a judicious manner that does not have serious, unintended consequences that will damage advancements in the safe delivery of patient care. A balance must be achieved between the goals of transparency and quality improvement.

Furthermore, we are extremely disappointed that CMS would include such a serious provision, one that warrants broad stakeholder commentary and that would affect all types of providers and suppliers along the care continuum, in an *inpatient* payment rule of over 1820 pages in length that is also on a fast track due to its payment implications. We believe this runs counter to the new Administration's stated goals of reforming the rulemaking process to make it more transparent, rationale and effective. By placing this provision in a rule with a title of *Inpatient Prospective Payment System*, it is obscured from many stakeholders who should have the opportunity to comment -- including non-hospital health care organizations and notably, experts in patient safety and quality of care. A proposal of this magnitude deserves to have been proposed in a manner that made it apparent to a full stakeholder audience and was tied to a more appropriate comment period in order that due consideration could be given to the weighty issues that it raises.

Our specific comments on the survey release provisions, as well as on other areas of the proposed rule, are outlined below. Separately, we will be responding to the Request for Information on regulatory reform.

Proposed Changes Related to Survey and Certification Requirements

A. Proposed Revisions to the Application and Re-Application Procedures for National Accrediting Organizations (AOs), Provider and Supplier Conditions, and Posting of Survey Reports and Acceptable Plans of Corrections (PoCs)

> § 488.5(a)(21) A statement acknowledging that the organization agrees to make all Medicare final accreditation survey reports (including statements of deficiencies) and acceptable plans of correction publicly available on the organization's Web site within 90 days after such information is made available to those facilities for the most recent 3 years, on an ongoing basis. This acknowledgement includes all triennial, full, follow-up, focused, and complaint surveys, regardless of whether they are performed onsite or offsite.

The Joint Commission's Comments:

The Joint Commission is a supporter of transparency in health care but is in strong opposition to this provision for the reasons that are detailed below. We urge CMS to sit down with all accrediting bodies to discuss the implications of this proposal on quality of care and to create a better pathway toward transparency. Because of the length of our comments in this section, we have added the following summation:

- The proposal will not be effective in helping the public and will not achieve the goal of beneficial transparency, but will come at great costs to quality and safety.

- The provision will adversely affect the collaborative efforts of accrediting bodies and healthcare organizations to improve patient safety and engage in continuous quality improvement. Ultimately, there will be increased patient harm and lower quality.
- There will be a chilling effect on accrediting body efforts to create new standards or raise the bar on compliance for existing requirements.
- There will be a race to the bottom on quality as health care organizations seek out oversight bodies that will report on the least number of standards comparable to the Medicare requirements. This may also lead to a growth in non-accredited facilities that will then be surveyed at taxpayer expense and with fewer oversight visits.
- The proposal will diminish the value of accreditation because it will lose the most significant and critical part of its mission: to inspire health care organizations to excel in providing safe and effective care.
- It will lay the foundation for an adverse dynamic between health care organizations and accreditation survey teams, characterized by pressures against making citations of deficiencies.
- The proposal will increase health care system costs. The proposal is extremely burdensome and costly for accrediting bodies and ultimately costly for health care organizations who will bear the brunt of the increases. This is in direct opposition to current efforts on regulatory reform and burden reduction in the health care system.
- The CMS proposal sets up an inherent legal conflict for accrediting bodies working with information under the Patient Safety and Quality Improvement Act of 2005.
- The proposal is not legal given the Medicare statutory language that protects accreditation survey reports from broad release by the Secretary.

Adverse Effect on Quality Improvement and Patient Safety

The Joint Commission is opposed to the CMS proposal to make all accreditation survey reports (including statements of deficiencies) and acceptable plans of correction publicly available on the websites hosted by accreditation organizations. As an organization whose mission is to support quality improvement and patient safety and inspire excellence, we believe the proposal will have significant detrimental consequences on our nation's ability to continually improve the delivery of health care services. To be clear, this opposition is not one against transparency, but one of creating the right balance between useful, publicly available information and improving the quality and safety of healthcare. The Joint Commission strongly supports the intent of the CMS proposal to provide actionable information to the public to assist in their healthcare decisions. The Joint Commission was the first in the nation to design a public program of standardized quality measures on specific hospital performance. Further, The Joint Commission has continuously published a large amount of information about its accreditation decisions and accredited health care organizations for more than 20 years. However, The Joint Commission does not believe the afore-stated CMS goal will be successfully accomplished by the proposal to make accreditation survey reports public. In distinction, we are very certain that its consequences will be harmful to the public's care.

The Joint Commission believes that there is a delicate balance between actions aimed at achieving transparency and actions meant to promote patient safety and reduce risks in health care. This balance has long been understood and revered in many industries that must deal with complex risks on a daily basis, such as in the oversight of aviation, rail and marine transportation, and commercial

nuclear power[1], to name only a few. All of these industries have a system of confidential reports that contain sensitive information reflecting on safety risks, solutions, and uncertainties around potential process failures. Importantly, these confidential components of oversight have been uniformly credited with raising the safety culture to successfully diminish preventable harm. They operate from the proven premise that strict adherence to regulatory requirements is not sufficient to achieve excellence in risk reduction—that more is needed to approach a state of high reliability.

These oversight systems, as well as many safety experts, peer review processes, and Congress (see legal analysis section), recognize that in order to achieve a reduction in harm in the provision of services, it is essential that some component of the system allows for the surfacing of risks – real and potential—to be discussed in a safe harbor that is free from the fear of reprisal, public humiliation, or litigation. There is a strong body of science around achieving high reliability in inherently risky environments that underscores that confidential interchanges over risks are a cornerstone of a safety culture; one that is symbolized by trust between those who carry out daily activities and the overseers of their actions. Accreditation is that trusted partner with its health care organizations and The Joint Commission accreditation survey reports are designed to capture that candid dialogue about safety risks with our survey team. This no-holds barred discourse with surveyors that we have been actively promoting as part of safety culture, allows us to work closely with our accredited organizations to help address their risks and any barriers to improvement within their organization. Today, we see organizations eager to solve their issues and actively engage our surveyors in order to better understand pathways to excellence. The CMS proposal will severely damage that trusted relationship.

Relatedly, The Joint Commission survey reports -- because they are confidential -- create a framework for the collective public good. The confidential nature of our survey process has a benefit that transcends assisting individual facilities with their problems. As a result of the honest discourse noted above about safety risk and challenges to improvements, The Joint Commission gleans valuable information to inform its accreditation program requirements and its information, technical assistance, and resource tools, such as The Joint Commission accreditation standards; National Patient Safety Goals; Sentinel Event Alerts; Quick Safety publications; help with Root Cause Analyses; and performance expectations during the survey process. Thus, the ability to gain knowledge and to learn from our organizations within the safe harbor, eventually creates a benefit that flows to all organizations and to their patients. This is a collective good that would not be possible without the ability to encourage an honest and open dialogue with health care facilities that may otherwise be reticent to raise concerns for fear disclosure of sensitive information.

Equally important, the release of accreditation reports will have a chilling effect on continuously raising the bar on quality of care. Accrediting bodies compete against each other on how well they serve their customers in achieving quality and patient safety. With the release of

[1] Specifically, the Institute of Nuclear Power Operations (INPO) was designed with intent to "establish a program that specifies appropriate safety standards including those for management, quality assurance, operating procedures and practices, and that conducts independent evaluations." INPO became the private sector partner to the government that the presidential commission had envisioned; analogous to Congress' intent of creating a public-private partnership with accrediting bodies. INPO's survey reports and other information with its members are strictly confidential. The information is not shared with the Nuclear Regulatory Commission (NRC) or the public. This is viewed by INPO as vital to the success of its mission. INPO likens the need for confidentiality to the "doctor patient relationship, requiring a high level of confidentiality to carry out essential tasks. Utilities are more willing to set challenging goals and to strive for excellence if they know they will not be criticized publicly if they fall short of these challenging goals."

accreditation survey reports, there will be a disincentive for any accrediting body to go beyond its competitors in challenging its accreditation family, for fear that its own accredited organizations will fare worse in the public eye. For example, The Joint Commission has vastly more hospital standards and requirements than those of the Medicare program, and each of these additional requirements may be viewed as another opportunity for Joint Commission accredited hospitals to look worse on performance. It is not unreasonable to predict that health care organizations will shy away from such opportunities and take their business to the accrediting body with the least number of additional requirements or simply become non-accredited. This will put a pause to accrediting bodies as they consider whether new, state-of-the-art requirements should be imposed when they know that compliance will be demanding for the first few years of implementation. Even as accreditors apply the Medicare standards related portion of their program, there will be a disincentive to continually challenge the compliance with those standards against higher levels of performance if not done equally among the competing accreditors and the state survey agencies acting on behalf of the government.

Culture of Compliance

The hesitancy of accrediting bodies to raise the bar on quality and safety expectations as a result of this provision, combined with the hesitancy of health care organizations to air their most sensitive risks and problems in reaching their goals will incentivize a race to the bottom on quality. As stated earlier, some organizations will choose accrediting bodies with the fewest standards beyond those of the threshold Medicare conditions of participation; and possibly seek out the accrediting body with the least stringent requirements for compliance. Or they may see a significant benefit in migrating away from accreditation altogether to move to a free government survey that occurs at a frequency less often than those required by accreditors. There is a risk of reverting to a mindset that complying with government regulations is enough and that they are the upper limits of quality and safety, without the need to be exceeded. A similar culture of compliance has been seen historically in a number of industries, and it has been the cause of notable industrial accidents. These industries have learned from these sad experiences and have embraced the need for an oversight framework that brings in both safety culture and a vision of what the "perfected" looks like – analogous to how accrediting bodies view their role and mission. **The CMS proposal threatens an advent in health care of a culture of compliance, characterized by failure to go beyond the minimum required by regulations.**

Effect on Transparency

The CMS proposal will not advance the goal of transparency. Effective transparency is not about pouring more unfiltered information into the marketplace, but it is accomplished best by discerning what types of information would be most useful for the public and then ensuring a fair opportunity for that information to be understood and placed into context. Otherwise it is not information, but rather just data without translation as to its significance and with very limited public utility.

To underscore the need to stop and consider what is best for achieving transparency, we wish to point out that Joint Commission accreditation reports are not summaries or descriptors of quality specific to an organization. There is an inherent unfairness of the reports to accredited organizations if placed in the public marketplace, because they are quite unilateral, only focusing on areas needing improvement. Therefore, they do not contain an assessment for patients as to how well an organization may be performing in many of its areas of service. For example, a hospital may be

exemplary in its practices around surgical care and infection prevention protocols, but that will not show up in the survey report. Nor do the reports provide context or benchmarks for consumers around the areas called out in the report as needing improvement. It is actually a disservice to the public to provide reports that cannot be utilized for putting specific facilities of interest into a normative perspective. Again, this is because the reports are created for a very different purpose. Moreover, there is no standardization among the reports from accrediting bodies. Thus trying to compare the performance of two ambulatory surgery centers accredited by different accrediting bodies could be a futile exercise and extremely frustrating.

CMS survey reports are also poorly designed for public use. They are enforcement related documents with no comparability to accreditation reports. Therefore, the CMS rationale that the proposal to require release of accreditation survey reports will create equity with the government's release of its 2567 survey reports is misguided. We support the CMS intention to have more useful information available to the public that is congruent with information about non-accredited organizations. However, to get to that result, it will take, at minimum, a discussion between CMS and accrediting bodies; creation of a standardized format given the variability among accrediting bodies in their formats and standards; testing with the public; and significant time and monetary resources. The Joint Commission stands ready to enter into that dialogue with CMS.

In sum, accreditation survey reports are not just another piece of data to be made public to assist consumer choice. They are not designed for that purpose. They are quality improvement tools that contain sensitive information. **Accreditation survey reports are not at all analogous to the CMS reports that contain only enforcement related data and that do not serve as quality improvement tools. Accreditation survey reports are not the proper vehicle to use for achieving Transparency goals.**

Proprietary Content

The Joint Commission is concerned CMS' proposal will expose proprietary information. Survey reports may contain facility specific proprietary information, such as whether an organization is going to build a new outpatient department or invest in specific equipment, or has resource issues. Organizations may identify that they are financially challenged to update aspects of their physical plant. Or conversely, that they plan to extend their services into the community. **This display of information may cause them to have a competitive disadvantage within their sector if other facilities or corporations act on such information by engaging in similar actions or a marketing campaign against the facility**. Facilities may state information within their plan of correction such as the need to purchase additional sterilizers, infusion pumps, etc. This may also cause other facilities to be aware of their financial situation or hardships.

The redaction of the above types of information is possible, but must be done manually and at great cost. Redaction may lead to its own unintended consequences; as the public will be required to piece together information and may have to make assumptions of what is redacted. Consequently, The Joint Commission believes accrediting bodies will also receive an increased call volume from consumers regarding the survey reports and acceptable plans of correction to gather more information and/or to better understand the information that was made available.

While facility related proprietary information can go through an arduous and costly manual redaction process, the accreditation survey reports regardless of redaction expose

accrediting bodies to the disclosure of competitive information, such as the wording of standards, process requirements, and other intellectual property. The Joint Commission's survey reports, outside of their technical nature, contain the language and structure of our standards across the various chapters within our accreditation manuals as well as proprietary patient safety tools, survey techniques, and analytics developed by The Joint Commission over many years and designed to assist facilities in achieving compliance and identifying risk. The Joint Commission believes that public release of our survey reports, (including statements of deficiencies) will require our business to release proprietary standards, business rules, and intellectual property which may have a damaging effect on our competitive advantage in the field.

Cost and Burden of this Proposal

The CMS proposal to require accrediting bodies to post on their websites an array of survey reports, corrective action plans, and complaint information will be incredibly onerous and costly to both accrediting bodies and to accredited health care organizations who ultimately will bear the costs in higher accreditation fees. **We believe such an onerous proposal is in direct conflict with the goal of this Administration to lower the costs in the system and to reduce burden on private sector stakeholders working with the government**. Because The Joint Commission is by far the nation's largest health care accrediting body with more than 21,000 entities in its accreditation and certification family, the costs of making public the vast amount of information, including offsite reviews and plans of correction, to the public is in the many millions of dollars a year. For a not-for-profit, this eventually will translate into both loss of accredited facilities (which is a loss of public good) and lost opportunities to use Joint Commission resources to assist health care organizations on new safety risks and complex quality issues -- information anticipated and used eagerly by many stakeholders in the health care system.

It bears stating that the government derives significant financial benefit from relying upon the work of accrediting bodies without cost to the taxpayer. As CMS has stated, the number of accredited organizations participating in Medicare has risen, and each of these additional accredited organizations represents lower government outlays. In recent years, there have been increasing demands placed by CMS on accrediting bodies without regard to the effects on its ability to carry out its not-for-profit business. **This proposal would create an even larger financial burden that would substantially impair the ability of accrediting bodies to carry out their quality mission.** At some point, the increased cost of accreditation resulting from undue government regulation will make accreditation unsustainable for many organizations.

The Joint Commission would have to engage in significant work to comply. That work would also be ongoing. We expect a significant uptake on public calls to The Joint Commission asking for explanations around content in the survey reports as well as calls from Capitol Hill, health care organizations, lawyers, and researchers. Information systems would need to be upgraded or changed. Each survey report would need to be evaluated for inclusion of patient identifiable information, proprietary information, and other identifiers of health care staff – requiring redaction processes. An analysis was conducted to determine as closely as possible the costs which would result from the implementation of the proposed requirement to post all Joint Commission survey reports and related information. The analysis was based on some broad assumptions and an eighteen month implementation plan. Overall, the analysis shows first year, start-up costs of almost $4 million dollars, with more than $2 million dollars in expense in each subsequent year. These are dollars that would be diverted from other quality and safety initiatives.

Given the set of working assumptions listed below, the estimated five year total additional expense to support this public reporting proposal is $13,277,000.

2017 and 2018 together: $3,977,000
2019: $2,275,000
2020: $2,375,000
2021: $2,275,000
2022: $2,375,000

Assumptions:

- Reporting would begin with surveys conducted in 2019 and would not include any historical information.
- A customized portal would be developed with user registration and search capabilities.
- New software would be implemented to remove PHI from the reports. This would also be added to all surveyor software. Additional staff would be required to manually review all reports to ensure that no competitive/proprietary information is embedded within a report.
- Additional automated management tools would be required to enable the business to perform timely administrative functions for thousands of reports and updates.
- Standards would be restated making the reports more user friendly for consumers.
- Public reporting would probably result in additional complaints for evaluation by our Office of Quality Monitoring and Patient Safety requiring a 20% increase in staff.
- Additional staff would be required to respond to Congressional inquiries/requests and state legislative inquiries.
- Additional communication support would be needed to explain the reporting process and respond to media inquiries.
- Additional training would be required for all customer-facing staff to ensure standardization of the documentation of observations/findings under the new reporting structure. Other staff would be trained on how to respond to customer inquiries/concerns.
- Customer focus groups would be conducted to gather feedback on the usability of the reports.

Legal Analysis

CMS's proposal may not be finalized because it relies on an unlawful interpretation of the agency's authority under section 1865 of the Social Security Act. **CMS's proposal would impermissibly contravene Congress's clear intent to protect the confidentiality of final accreditation survey reports from broad public disclosure under section 1865(b).**[2]

In the Proposed Rule, CMS contends that it has the authority to require public reporting of accreditation surveys by AOs under section 1865(a)(2), which permits the Secretary to consider "other factors" when determining whether an AO should be granted deeming authority.[3] But

[2] *See generally Chevron v. NRDC*, 467 U.S. 837, 843 (1984) (when the intent of Congress is clear, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress").

[3] SSA § 1862(a)(2) (also enumerating specific factors for consideration); *see* 82 Fed. Reg. at 20,143. The Proposed Rule suggests that CMS may consider whatever "other factors" it wishes when determining whether an AO should be granted deeming authority. *See* 81 Fed. Reg. at 20,143. This is not the case. Among other things, under the "*ejusdem*

CMS's discretion to determine the requirements for deeming authority is not unlimited.[4] "In ascertaining whether [an] agency's interpretation is a permissible construction of [statutory] language, a court must look to the structure and language of the statute as a whole."[5] And section 1865(b) plainly provides that "the Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by . . . any [] national accreditation body, of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary."[6]

Section 1865(b)'s confidentiality safeguard is clearly intended to prevent the Secretary from effectuating the broad public disclosure of confidential accreditation survey reports. Yet the Proposed Rule seeks to interpret section 1865(a)(2) in a manner that would deprive section 1865(b) of any meaningful effect. Such a construction of the statute cannot be sensibly reconciled with the statutory text and Congress's plain intent. Courts "require legislative history of exceptional clarity" to support "an interpretation which . . . would deprive [a statutory provision] of virtually all effect.' . . . [W]hatever ambiguities exist in [a statutory regime]" do not justify an agency adopting such an interpretation where "[t]he legislative history . . . fails to indicate that Congress intended [] such perverse effects."[7]

An examination of the legislative history here reveals no such "exceptionally cl[ear]" support for CMS's proposed interpretation.[8] Historically, AOs have "maintained strict confidentiality of [all] information provided to them and of information generated in the accreditation process," in order to encourage full disclosure during the accreditation review process.[9] "The original 1965 Medicare statute . . . did not [even] authorize [the Secretary] . . . to seek disclosure of accreditation information" from AOs,[10] and "[The Joint Commission] . . . consistently refused to release its

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generis rule of construction[,] . . . general words are confined to the class" of specifically enumerated words to which they are attached in a statute, "and may not be used to enlarge" the statutorily enumerated class. *Cleveland v. United States*, 329 U.S. 14, 18 (1946). As reflected in the Proposed Rule, *see* 81 Fed. Reg. at 20,143, the specifically enumerated class of factors that CMS must consider all relate to whether an AO imposes on providers accreditation or survey requirements that meet or exceed Medicare requirements, or whether the AO has sufficient resources to monitor or enforce its requirements or furnish data to CMS to demonstrate that it has done so. *See* SSA § 1865(a)(2). The general "other factors" that CMS may consider must be confined to this statutorily enumerated class of factors and therefore must relate to how an AO requires providers to meet or exceed Medicare requirements or demonstrates that it is ensuring that providers meet these requirements. To the extent that CMS proposes to consider "other factors" that do not fall within this class of factors – and that instead, for example, serve an unrelated public transparency objective – its proposal runs afoul of longstanding principles of statutory construction.

[4] *Cf. Ry. Labor Execs.' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 670 (D.C. Cir. 1994) (agencies do not "possesses *plenary* authority to act within a given area simply because Congress has endowed it with *some* authority to act in that area") (emphasis in original), *amended to correct typographical errors*, 38 F.3d 1224 (D.C. Cir. 1994).

[5] *Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 417 (1992).

[6] SSA § 1865(b).

[7] *Am. Fed. of Gov't Emps., AFL-CIO v. Fed. Labor Relations Auth.*, 798 F.2d 1525, 1528–30 (D.C. Cir. 1986) (internal citations omitted); *see also Bennett v. Spear*, 520 U.S. 154, 173 (1997) ("It is the cardinal principle of statutory construction . . . to give effect, if possible, to every clause . . . of a statute . . . rather than to emasculate an entire section.") (internal quotation marks omitted); *Halverson v. Slater*, 129 F.3d 180, 185 (D.C. Cir. 1997) (rejecting an agency interpretation that "runs afoul of the cardinal canon of statutory construction that '[w]e must read statutes to give effect to each [provision] if we can do so while preserving their sense and purpose'") (internal citations omitted).

[8] *Am. Fed. of Gov't Emps., AFL-CIO*, 798 F.2d at 1529.

[9] Timothy Jost, *Confidentiality and Disclosure in Accreditation*, 57 L. & CONTEMPORARY PROBLEMS 171, 171 (1994) (describing the legislative history of section 1865).

[10] *Id.* at 174.

survey forms to anyone other than the institution surveyed."[11] This did not change until 1972, when section 1865 was added. As originally enacted, section 1865 required "[The Joint] Commission to release to the Secretary (on a confidential basis) upon his request (or such State agency as the Secretary may designate) a copy of the most current accreditation survey of such institution made by such Commission."[12] "The obvious intention of Congress in making th[e] change in law was to induce, by guaranteeing their confidentiality, [The Joint Commission] to provide its surveys to the Secretary so that he would have the means to compare [The Joint Commission's] accreditation decisions with Medicare standards otherwise applicable."[13] And the most "read[]y . . . interpretation" of the original statutory text is "that information so furnished is not to be made public but may be conveyed to the Congress on proper request."[14] Thus, in enacting section 1865, Congress acceded to the notion that accreditation surveys would remain protected against broad *public* disclosure; as originally enacted, section 1865 was intended to require The Joint Commission to furnish its confidential survey reports *to the Secretary* – and *only* to the Secretary – so long as the Secretary agreed to maintain the confidentiality of such reports.[15]

The subsequent amendments to section 1865 leave this core purpose unchanged. In 1984, Congress amended section 1865 to more closely resemble the statutory language found in the current version. As illuminated by the conference report associated with the 1984 amendment, the purpose of the revision was simply to extend the guarantee of confidentiality to other AOs, beyond The Joint Commission.[16] Then, in 1989, Congress again amended section 1865, through the Omnibus Budget Reconciliation Act of 1989, to create a limited exception to the confidentiality requirement when accreditation survey reports relate to an enforcement action taken by the Secretary.[17] Notably, the 1989 exception in no way otherwise altered Congress's accession to the status quo that accreditation surveys remain protected against broad public disclosure. Under the exception, "[t]he Secretary would only be authorized to release accreditation reports and related information if the material related to an enforcement action taken by the Secretary."[18] "This [narrow] exception is based on the

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[11] Contempt Proceedings Against Sec'y of HEW Joseph A. Califano, Jr., 95th Cong., Comm. Print No. 95-76, at 60–61 (Aug. 16, 1978).

[12] *An Act to Amend the Social Security Act*, Pub. L. No. 92-603, 86 Stat. 1329, 1423 (1972).

[13] Contempt Proceedings Against Sec'y of HEW Joseph A. Califano, Jr., 95th Cong., Comm. Print No. 95-76, at 60–61 (Aug. 16, 1978) (post-enactment statement of the Secretary describing the purpose of section 1865's confidentiality provision).

[14] *Obligation to Produce Deficiency Letters Received from the Joint Comm'n on Accreditation of Hosps. to Comms. of Cong.*, 43 U.S. Op. Atty. Gen. 36, 38 (1975).

[15] In 1975, the Department of Health, Education, and Welfare (HEW) released copies of accreditation decision-related letters in response to a Freedom of Information Act (FOIA) request, and the Joint Commission sued to maintain the confidentiality of its accreditation documents. In the subsequent settlement, HEW agreed not to release accreditation letters or accompanying recommendations or comments. HEW, the predecessor to the Department of Health and Human Services, thereby acceded to the understanding that accreditation materials were intended to be confidential under section 1865, even against FOIA requests. *See* Timothy Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?* 57 L. & CONTEMPORARY PROBLEMS 15, 19 & n.32 (1994) (citing *Joint Comm'n on Accreditation of Hosps. v. Weinberger*, No. 75-CV-175 (N.D. Ill. Oct. 8, 1975)).

[16] *See* 130 Cong. Rec. 18,418 (June 22, 1984) (["The original] law contain[ed] certain disclosure safeguards relating to survey information used by the Secretary in connection with the hospital certification process under Medicare. However, the law only specifically referr[ed] to surveys conducted by the Joint Commission.").

[17] *See* Pub. L. No. 101-239 § 6019(b), 103 Stat 2106, 2166. Accreditation surveys with respect to home health agencies are also excepted from section 1865(b)'s confidentiality safeguard. *See* SSA § 1865(b). The home health agency exception was added in 1987. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203 § 4025(b), 101 Stat 1330, 1374.

[18] H. Rep. No. 101-247, at 988 (1989).

obvious fact that the government cannot take enforcement action based on adverse accreditation information unless it is able to introduce in subsequent proceedings evidence gained from accreditation agencies."[19]

Congress clearly did not intend to authorize the Secretary to circumvent completely section 1865(b)'s confidentiality safeguard. As the above-described legislative history makes plain, Congress's enactment of section 1865(b), and its statutory predecessors, makes sense only if Congress determined that AOs should have the discretion to keep accreditation survey reports confidential, except in the narrow circumstances specified in the statutory text of section 1865(b) itself. There would have been no point for Congress to establish section 1865(b)'s confidentiality safeguard if section 1865(a) gave the Secretary plenary discretion to require AOs to publicly disclose confidential accreditation survey reports on the Secretary's behalf.

CMS may not permissibly endorse an interpretation of the Social Security Act that renders section 1865(b)'s guarantee of confidentiality nugatory. It is an "elementary canon of construction that a statute should be interpreted so as not to render one part inoperative,"[20] "void[,] or insignificant."[21] CMS's proposal violates this cardinal rule of statutory interpretation by reading section 1865(a)(2) to give the Secretary discretion to require AOs to make public accreditation survey reports that the Secretary is himself statutorily required to keep confidential under section 1865(b).[22] A construction of the Social Security Act that permits an agency to "unilaterally create . . . [] event[s] that would render another statutorily-specified [guarantee] . . . meaningless . . . is not a plausible reading of [a] statute."[23] CMS's public reporting proposal represents a patently unreasonable and therefore unlawful interpretation of the Social Security Act and may not be finalized.

The CMS proposal sets up an inherent legal conflict for accrediting bodies working with information under the Patient Safety and Quality Improvement Act of 2005.

To encourage the reporting and analysis of medical errors and prospective risks of harm to patients, the Patient Safety and Quality Improvement Act of 2005 (PSQIA) provides Federal privilege and confidentiality protections for patient safety information. The PSQIA creates a protected environment where providers may report and examine patient safety events without fear of increased liability risk or public shaming. Safety related data under this Act is called *patient safety work product* (PSWP) which encompasses a large spectrum of risk related information, reports, and analyses. Congress wished to create a non-punitive, quality improvement framework that would

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[19] Jost, *Confidentiality and Disclosure in Accreditation*, *supra*, at 178.
[20] *Colautti v. Franklin*, 439 U.S. 379, 392 (1979).
[21] *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (internal quotation marks and citations omitted); *cf. Massachusetts v. EPA*, 127 S. Ct. 1438, 1462 (2007) (agency discretion must be "exercise[d] . . . within defined statutory limits[;] . . . [agency] 'judgment' is not a roving license to ignore the statutory text") (enforcement discretion context).
[22] *Cf. American Tobacco Co. v. Patterson*, 456 U.S. 63, 71 (1982) (rejecting an agency interpretation of a statutory provision that made it illegal to adopt, and in practice to apply, seniority systems that fell within the class of systems protected by the statutory provision); *see also New York State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 419–20 (1973) (statutes should "'not be interpreted to negate their own stated purposes'").
[23] *Bennett v. Donovan*, 4 F. Supp. 3d 5, 14 (D.D.C. 2013) (rejecting an agency's interpretation of a reverse mortgage insurance statute where the agency relied on a statutory grant of authority to specify "other [triggering] events" to defend the creation of a triggering event that made the statutorily enumerated triggering event "meaningless"); *cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 485 (2001) (agencies "may not construe the statute in a way that completely nullifies textually applicable provisions meant to limit its discretion"); *Nat'l Treasury Emps. Union v. Chertoff*, 452 F.3d 839, 858 (D.C. Cir. 2006) (agencies may not "nullify [a] statute's specific guarantee[s]").

encourage health care organizations to surface their issues within its safe harbor. The expectation was that this protected environment would yield increased data and a better understanding of patient safety events."[24] Congress attached significant civil monies penalties to wrongful disclosure of this information in order to fortify the information's protected status.

Congress expressed its intent in the statutory language that such sensitive PSWP, including root-cause analyses, could be shared with accrediting bodies and not lose the legal privilege and confidentiality protections conferred upon it. They recognized the critical, peer review-like role that accrediting bodies play in using that information to assist health care organizations with understanding system breakdowns and to guide them toward appropriate solutions. Therefore, Congress created an explicit statutory exemption for health care organizations to engage their accrediting bodies in reviewing this sensitive, protected patient safety information under the Act and helping them improve. In distinction, Congress deliberately eschewed providing the federal government – specifically CMS – with a similar exemption to receive *patient safety work product* because of the CMS enforcement role. **The PSQIA further strengthened the positon of accrediting bodies as quality improvement organizations, not analogous to the enforcement-only CMS survey and certification construct.**

The CMS proposal to require publication of a broad array of accreditation reports both threatens the ability of accrediting bodies to receive or review onsite patient safety work product per the PSQIA and places accrediting bodies in jeopardy of substantial monetary fines should PSWP be inadvertently disclosed. Health care organizations will be very reticent to share PSWP with their accrediting bodies if the CMS proposal is finalized. Consequently, this is yet another way in which the CMS proposal will lessen our nation's journey toward zero harm and higher quality care.

Recommendation to CMS

We strongly urge CMS to withdraw this proposal and engage in a serious dialogue between the government and the private sector accrediting bodies as to what would be useful information for the public and subsequently create a path toward that end. The Joint Commission has been a leader in transparency as mentioned above in connection with its hospital performance measurement program and continues to provide the most information of any health care accrediting body through its Quality Check® website. We do not shy away from transparency but we stand firmly for quality improvement and patient safety. We recommend that CMS revisit this proposal and work with AOs, consumers, and other stakeholders on an initiative to identify what information can be best utilized by the public rather than simply releasing the raw survey reports and plans of correction.

Proposed Changes Related to Quality Data Reporting Requirements for Specific Providers and Suppliers

A.1.d. Accounting for Social Risk Factors in the Hospital IQR Program

CMS is seeking public comments on whether it should account for social risk factors in the Hospital IQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. In, addition seeking public comments on

[24] https://www.hhs.gov/hipaa/for-professionals/patient-safety/index.html

which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure.

The Joint Commission's Comments:

The Joint Commission appreciates the opportunity to comment on whether CMS should account for social risk factors in the Hospital IQR Program. The Joint Commission is discussing and exploring methodologies to account for social risk factors, however, we do not have a methodology to share at this point in time.

A.8.a. Proposed Changes to Policies on reporting of eCQMs

CMS summarizes the main concerns identified by data submitters, including the following; "Hospitals have had challenges with data mapping (aligning the information available in an electronic health record (EHR), particularly if the information is not located in a structured field (for example, PDF attachment, free text section) to the required fields in a QRDA Category I (QRDA I) file), and workflow (the process of extrapolating the pertinent patient data from an EHR, transferring that data to a QRDA I file, and submission of the QRDA I file to CMS) because hospitals still need to collect CY 2017 data while still reporting CY 2016 data."

The Joint Commission's Comments:

The Joint Commission agrees that hospitals face multiple challenges when implementing and reporting eCQMs, and has conducted Voice of the Customer survey studies to further define and evaluate these challenges. Based on these efforts, The Joint Commission suggests CMS clarify the definition of workflow, which is separate but related to technical challenges, and consider how CMS might further support industry efforts to address both the technical and workflow challenges hospitals face.

Specifically, CMS has defined workflow as "the process of extrapolating the pertinent patient data from an EHR, transferring that data to a QRDA I file, and submission of the QRDA I file to CMS. The Joint Commission suggests that the use of "workflow" is not appropriate in defining the process of data extraction and QRDA I submission.

The Joint Commission suggests CMS separately define "workflow" and "data submission," as both pose challenges for hospitals reporting eCQMs.

Data Submission

Related to eCQM submission, in a March 2016 Voice of the Customer Survey, only 48% of hospitals reported they could extract all data required to report eCQMs, 55% reported they could map to required standard vocabularies, and 22% had successfully generated a QRDA I file. These findings demonstrate that data submission- the technical process of mapping, extracting, and submitting data, remains a challenge.

Workflow

AHRQ provides the following definition of workflow: "Workflow is the sequence of physical and mental tasks performed by various people within and between work environments. It can occur at several levels (one person, between people, across organizations) and can occur sequentially or simultaneously."
(https://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/workflow)

Hospitals report several factors related to eCQMs ultimately impact clinical workflow. Common challenges reported include the addition of EHR documentation outside of the normal provider workflow to meet reporting requirements, interruption in care processes or clinical decision making related to integration of data collection within the clinical workflow.

Through the Pioneers in Quality™ program, The Joint Commission seeks to address hospital needs related to both technical challenges and the need to share workflows and best practices, and encourages CMS to consider how CMS might support current and future efforts to address these needs.

A.9.d. (1) Safe Use of Opioids-Concurrent Prescribing Measure

Inviting public comment on the possible future inclusion of this opioid prescribing measure in the Hospital IQR Program:

- The Safe Use of Opioids – Concurrent Prescribing (MUC16-167) measure assesses patients (excluding cancer patients or patients receiving palliative care), ages 18 years and older with active, concurrent prescriptions for opioids, or opioids and Benzodiazepines, at discharge

The Joint Commission's Comments:

The Joint Commission supports the measure concept to assess prescribing opioids to patients already using an opioid or patients using benzodiazepine, as well as the need for medication reconciliation in all health care settings.

The Joint Commission is concerned that the measure may introduce unintended consequences, such as under treatment and placing undue accountability on acute settings for long-term pain management. There are circumstances in which it may be appropriate for patients to be treated concurrently with opioids and benzodiazepines, i.e., certain orthopedic procedures. It is recommended that the measure provides for the exclusion of cases in which polypharmacy may be warranted.

A.9.d. (2) Malnutrition Measures

Inviting public comment on the possible future inclusion of one or more of the malnutrition measures in the Hospital IQR Program:

- Completion of a Malnutrition Screening within 24 Hours of Admission (MUC16-294);
- Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening (MUC16-296);
- Appropriate Documentation of a Malnutrition Diagnosis (MUC16-344); and
- Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment (MUC16-372).

The Joint Commission's Comments:

The Joint Commission appreciates the opportunity to submit comments in support of inclusion of this suite of malnutrition measure in the Hospital Inpatient Quality Reporting Program (MUC16-294, MUC16-296, MUC16-344 and MUC16-372) addressing malnutrition developed by Avalere and the Academy of Nutrition and Dietetics.

Joint Commission standards have long reflected the importance of nutrition screening, assessment of at-risk hospitalized patients, diagnosis of malnutrition and appropriate intervention. Malnutrition is an ongoing healthcare issue with demonstrated impacts on patient outcomes. The Joint Commission welcomes the advent of performance measures to quantify the degree to which these best practices are carried out.

These evidence-based measures were developed in accordance with a rigorous, multi-stakeholder process. They have been completely tested and have been shown to have the capacity to significantly improve the health and well-being of patients.

A.9.d. (3) Tobacco Use Measures

Inviting public comment on the possible future inclusion of one or more of the eCQM versions of these tobacco use measures in the Hospital IQR Program. In addition, inviting public comment on the possible future inclusion of a composite measure comprised of all or a subset of these individual tobacco use measures in the Hospital IQR Program:

- Tobacco Use Screening (TOB-1) (MUC16-50);
- Tobacco Use Treatment Provided or Offered (TOB-2)/Tobacco Use Treatment (TOB-2a) (MUC16-51); and
- Tobacco Use Treatment Provided or Offered at Discharge (TOB-3)/Tobacco Use Treatment at Discharge (TOB-3a) (MUC16-52).

The Joint Commission's Comments:

The Joint Commission strongly supports the inclusion of the three Tobacco Use eCQMs in the Hospital IQR Program. In the FY 2017 IPPS proposed rule, CMS had requested comments on potential measures for behavioral health in the Hospital IQR Program. The Joint Commission had shared in our comments for the FY 2017 proposed rule that Tobacco Use is not limited to patients in psychiatric facilities. Hospitalization (both because hospitals are a tobacco-free environment and because patients may be more motivated to quit as a result of their illness) offers an ideal opportunity to provide cessation assistance that may promote the patient's medical recovery.

The Joint Commission has significant experience with tobacco measures and has included the chart-based Tobacco Use measures for selection in our ORYX performance measurement reporting program since 2012. The Joint Commission has been actively involved with the CMS subcontractor responsible for the retooling of these measure to eCQMs.

The Joint Commission has concerns about consideration for possible future inclusion of a composite comprised of all or a subset of the individual Tobacco Use measures. At present the Tobacco Use measures focus on 3 distinct intents, Screening, In-patient treatment and Out-patient treatment. The all-or-none scoring of a composite measure could potentially dilute the quality improvement aspect of the measures. It is felt that this would be less burdensome for hospitals to identify where improvement is required if the measures remain separate as opposed to determining deficiencies within a composite measure.

A.9.d. (4) Substance Use Measures

Inviting public comment on the possible future inclusion of one or more of the eCQM versions of these substance use measures in the Hospital IQR Program. In addition, inviting public comment

on the possible future inclusion of a composite measure comprised of all of these individual substance use measures in the Hospital IQR Program:

- Alcohol Use Screening (SUB–1) (MUC16-179);
- Alcohol Use Brief Intervention Provided or Offered (SUB–2) /Alcohol Use Brief Intervention (SUB-2a) (MUC16-178); and
- Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge (SUB–3)/Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB-3a) (MUC16-180).

The Joint Commission's Comments:

The Joint Commission strongly supports the inclusion of the three Substance Use eCQMs in the Hospital IQR Program. In the FY 2017 IPPS proposed rule, CMS had requested comments on potential measures for behavioral health in the Hospital IQR Program. The Joint Commission had shared in our comments for the FY 2017 proposed rule that Substance Use is not limited to patients in psychiatric facilities. Given the heightened awareness of the opioid epidemic, inclusion of the SUB measures in the Hospital IQR program would address this serious health care issue.

The Joint Commission has significant experience with Substance Use measures and has included the chart-based Substance Use measures for selection in our ORYX performance measurement reporting program since 2012. The Joint Commission has been actively involved with the CMS subcontractor responsible for the retooling of these measure to eCQMs.

The Joint Commission has concerns about consideration for possible future inclusion of a composite comprised of all or a subset of the individual measures. At present the Substance Use measures focus on 3 distinct intents, Screening, In-patient treatment and Out-patient treatment. The all-or-none scoring of a composite measure could potentially dilute the quality improvement aspect of the Substance Use measures. It is important to maintain the integrity of the quality improvement process and it is felt that this would be less burdensome for hospitals to identify where improvement is required if the measures remain separate as opposed to determining deficiencies within a composite measure.

Proposed Changes for Hospitals Excluded from the IPPS

(C)(3)(b) Critical Access Hospitals (CAHs) – Notice Regarding Changes to Instructions for the Review of CAH 96-Hour Certification Requirement

> In order to minimize the burden of documentation submission requirements for CAHs with respect to the 96-hour certification requirement, in this proposed rule, we are providing notice that CMS will direct Quality Improvement Organizations (QIOs), Medicare Administrative Contractors (MACs), the Supplemental Medical Review Contractor (SMRC), and Recovery Audit Contractors (RACs) to make the CAH 96-hour certification requirement a low priority for medical record reviews conducted on or after October 1, 2017. This means that, absent concerns of probable fraud, waste, or abuse with respect to the 96-hour certification requirement, these contractors will not conduct medical record reviews.

The Joint Commission's Comments:

The Joint Commission commends CMS on lessening the enforcement priority of the Critical Access Hospital requirement that each patient cannot exceed a 96-hour stay at the facility. However, The Joint Commission is concerned that this requirement remains to be a quality and safety condition of participation and therefore must be incorporated into accrediting body manuals for enforcement.

The Joint Commission believes that CMS should remove this requirement from the quality and safety conditions of participation and rely upon the fiscal intermediaries who currently make these calculations. Accrediting Organizations should not be required to enforce this requirement because is tailored towards payment certification and best made by CMS as part of its fiscal oversight.

Information Collection Requirement (ICRs) Relating to Survey and Certification Requirements

(C) Request for Information on CMS Flexibilities and Efficiencies

> CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule…
>
> We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers…

The Joint Commission's Comments:

The Joint Commission appreciates the CMS effort to include a Request for Information seeking public comments on ways to reduce regulatory burden and system costs, and to provide flexibility to the health care industry. In regards to this RFI, The Joint Commission would like to take the opportunity to comment on two major points:

- How CMS can reduce burden in a way that increases quality of care and reduces costs, and,
- Ideas that can influence regulatory, sub-regulatory, policy, practice, and procedural changes.

The Joint Commission believes that an appropriate regulatory balance needs to be struck between the public and private sectors with regard to the oversight of health care providers and suppliers; one that brings the strength of each sector to the oversight framework. With the right balance, the ultimate beneficiaries will be the patients who are served by both sectors. The private sector has the ability to be agile, constantly innovative, and aspirational in its ever increasing requirements– at no cost to the government - but in the context of voluntary accreditation programs. The federal government has the ability to set a powerful, national performance floor that is a mandatory threshold for those wishing to receive federal funds. The right regulatory balance can permit the government to take full advantage of private sector expertise in raising the national bar on quality and safety while allowing the force of government to ensure that continued, substandard performance is not permitted in federal programs.

The Joint Commission believes that to achieve the right public-private sector balance, some regulatory reform will need to be conducted. In our review, a number of regulatory provisions are holding back the ability for national progress in quality and patient safety. At the same time, a lack of alignment in oversight requirements between government and private sector accreditation is creating unnecessary burden. First, we are concerned that aspects of the CMS 2015 Final Rule entitled *Medicare and Medicaid Programs; Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures; Final Rule (CMS-3255-F; RIN: 0938-AQ33)* have lessened the benefits of the private sector's ability to innovate and establish state-of-the-art standards and survey methods. The implementation of this rule added significant regulatory restrictions to accrediting bodies by setting up a process that uses, as its yardstick, a one-to-one comparison of accrediting bodies and state survey agencies.

The CMS regulatory approach to rigidly impose the language of the Conditions of Participation (CoPs) on accreditation standards, and the survey methods found in the State Operations Manual to accreditation evaluations and follow-up, has made it difficult to accomplish our mission to "improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value." It has greatly lessened the ability of accrediting bodies to innovate with new standards and performance expectations. It also makes it difficult to always set follow-up requirements with timeframes appropriate to the types and levels of deficiencies found during surveys, as well as to set timeframes appropriate to ensuring sustainability of corrective actions.

Further, certain provisions of the aforementioned rule, such as the one requiring AOs to provide, in writing, notice to CMS of any proposed changes in accreditation requirements or survey process and refrain from implementing any changes before receiving the CMS approval, have caused delays in updated standards, survey processes, tools, and guidance documents for the field. For example, there is now a 60 day clock for CMS to respond that gets reset whenever CMS has questions or requires additional information. On cycle of this process can lead to an approximate delay of four and a half months, not including the time associated with The Joint Commission reestablishing publication timeframes. Updated standards that are not timely implemented may be lost opportunities for elevating quality and patient safety while lowering system costs.

By permitting accrediting bodies to have flexibility beyond the State Operations Manual (SOM), it permits accrediting bodies to use requirements that differ, but are more state-of-the art, when it is in the best interest of patients and staff. For example, the psychiatric hospital CoPs are 30 years old, yet The Joint Commission is unable to apply newer requirements that match the way psychiatric care is delivered today and in accordance with professionally recognized standards. This mismatch creates both high disparity rates with the government oversight surveys as well as burden and confusion in the field. We all appreciate the challenge confronting government to continually update every requirement, so using the private sector in a more flexible manner can be a major benefit to quality and safety at no cost to the government; it is also statutorily permissible.

Another recent example in which the regulatory philosophy caused difficulties in achieving continuous quality improvement, was the disapproval by CMS of a process for a health care facilities to self-identify physical plant and Life Safety Code deficiencies without triggering prescriptive and sometimes inappropriate plans of corrections. The Joint Commission embraced many good suggestions by CMS to tighten up the process, but the overwhelming CMS requirement that the process exactly mirror the SOM made it unworkable. Thus, we believe there is an opportunity for

the federal government to more effectively utilize the private sector to enhance the quality and safety for all patients.

The Joint Commission believes that such flexibility is directly congruent with Congress' original intent of the public-private partnership for deemed status authority. The AO framework was envisioned by Congress to bring to government programs, professionally recognized organizations with state-of-the-art standards, survey processes, and healthcare expertise to help propel quality and patient safety within the healthcare sector; while not adding any costs to the private sector. Even though Congress revised the Medicare statute in 2008 to eliminate mention of any specific AO and to move the oversight responsibilities from Congress to the executive branch; Congress' original philosophy was never altered. To this point, The Joint Commission believes CMS can and should leverage the AOs to augment CMS requirements to higher levels of quality and safety, rather than force congruency.

As The Joint Commission stated earlier a lack of alignment in oversight requirements and compliance expectations between government and private sector accreditation is problematic. The Joint Commission views the framework utilized by CMS in the oversight of the CMS Regional Offices as significantly different from that of the AOs. As stated by CMS, there is no direct line of authority between the CMS Survey & Certification department and the Regional Offices. This "dotted line" relationship allows Regional Offices to have a level of flexibility and autonomy to operate in the capacity best suited for the health care facilities and patients they serve. For example, the Regional Offices have created rules, policies, and interpretations of federal requirements that do not match the federal guidelines established by the CMS Central Office, and are sometimes inconsistent among them. The Joint Commission is concerned that this mismatch creates both high disparity rates with the government as well as burden and confusion in the field; it is also an inequity with expectations placed on the AOs.

Another regulatory area that the CMS should study is allowing AOs to utilize the most recent version of the Life Safety Code (LSC). The LSC is a compilation of fire safety requirements for new and existing buildings, and is updated and published every 3 years by the National Fire Protection Association (NFPA). On November 4, 2016, CMS adopted the 2012 edition after operating off the 2000 edition for 16 years. Since the adoption of the 2012 edition, the NFPA has released the 2015 version and we anticipate the 2018 edition later this year. The different iterations of the LSC bring forward modernized standards and new approaches to fire protection that offer areas of burden relief with the developed technology in the sector. As previously stated, The Joint Commission recognizes the challenges government faces with continually updating federal requirements. Therefore, The Joint Commission believes CMS has the opportunity to review this regulatory issue and better utilize the private sector to implement these next level protections prior to the official CMS adoption, which will create a major benefit to quality and safety at no cost to the government.

Moreover, CMS has the opportunity to reduce burden and overall system costs by reviewing the agency's internal evaluation process of the AO programs. As previously stated, AOs are required to provide any standards or survey process updates to CMS in writing. During this review process, CMS has taken the opportunity to not only review the submitted changes and any affected areas, but to also review other areas outside of the issue at hand. The CMS revisiting of areas already once approved creates a level of burden to both the AOs and CMS. The Joint Commission believes once an area of an AO's program has been approved, CMS should not re-review that area, unless the AO has made a change to it or CMS has identified a level of poor performance. Furthermore, The Joint

Commission believes the CMS review of topic areas should only occur within the accreditation deemed program approved by CMS. For example, The Joint Commission has many standards, processes, certification and other programs outside of the federal requirements. The Joint Commission believes that because these areas exceed the federal requirements, CMS should not review changes or additions to them.

In closing, there are opportunities for regulatory and process revisions to reduce burden, system costs, and provide flexibility to the health care industry in a manner that improves the delivery of care. The Joint Commission appreciates the opportunity to comment on the CMS Request for Information and stands ready to work with the agency in developing an oversight framework that not only supports the CMS oversight responsibilities but also allows for innovation and flexibility of the AOs in a mission to continuously improve quality and patient safety across the continuum of care.

The Joint Commission appreciates the opportunity to comment on this proposed rule, and is pleased to answer any specific questions you may have regarding our comments. Please do not hesitate to contact me directly or contact our Washington, D.C. office headed by Margaret VanAmringe, Executive Vice President for Public Policy and Government Relations. She can be reached at MVanamringe@jointcommission.org and at (202)783-6655.

Sincerely,

Mark R. Chassin, M.D., FACP, M.P.P., M.P.H.
President and Chief Executive Officer