

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality (CCSQ)

July 26, 2021

Michael Sroczynski
Senior Vice President, Government Advocacy & General Counsel
Massachusetts Health & Hospital Association
101 Arch Street, Suite 1741
Boston, MA 02110
E-mail: msroczynski@mhalink.org

Re: Petition for Review of CMS State Operations Manual (SOM), Appendix A, Regulations and Interpretive Guidelines for Hospitals for §482.12(b) CEO standard

Dear Mr. Sroczynski:

On March 16, 2021, we received a petition you submitted on behalf of the Massachusetts Health & Hospital Association to the U.S. Department of Health and Human Services (“HHS” or “the Department”) pursuant to the HHS Good Guidance Practices Regulation, 85 Fed. Reg. 78,770 (Dec. 7, 2020). *See also* 45 C.F.R. § 1.5(a). Your petition, attached as Exhibit A, pertains to the Centers for Medicare & Medicaid Services (“CMS”) Transmittal R37SOM dated October 17, 2008, which revised the State Operations Manual, Appendix A, Regulations and Interpretive Guidelines for Hospitals, to reflect amended regulations and survey certification policy issuances concerning Medicare Conditions for Participation for Hospitals at 42 CFR Part 482.

Specifically, your petition requests in accordance with 45 C.F.R. § 1.5(a)(2) that the Department modify Section A-0057 of Appendix A, because a State Survey Agency is using this guidance document to create additional legal obligations beyond what is required by the terms of 42 C.F.R. § 482.12(b). Your petition alleges that, in 2017, one of your member hospitals was found not to be in substantial compliance with 42 C.F.R. § 482.12 during a survey based on the survey agency’s incorrect interpretation of A-0057 to prohibit arrangements under which the same individual serves as the CEO of two hospitals within a system. It further alleges that this interpretation required the member hospital to implement its Plan of Correction changing its organizational structure to designate single individuals as CEOs for two separate hospitals in the system. Also, the petition requests the following modification to be added to the guidance at A-0057: “it does not matter that the CEO is also the CEO of other hospitals, as long as he or she fulfills all the responsibilities of a CEO at each of the hospitals.”

After review and consideration of these allegations and requests, while we agree that the State Survey Agency is interpreting Section A-0057 of Appendix A of the State Operations Manual to

create additional legal obligations beyond what is required by the terms of 42 C.F.R. § 482.12(b), we decline to modify Section A-0057. The current requirement at § 482.12(b) and corresponding surveyor guidance in Appendix A permits a CEO to serve multiple facilities and is intended to prevent several individuals from having the title of CEO at the same facility. Therefore, no changes to the surveyor guidance in Appendix A are necessary at this time.

Since neither the guidance nor regulation support the 2017 noncompliance deficiency citation that triggered this petition, CMS will follow-up with the member hospital identified in the petition and revise the Statement of Deficiencies and Plan of Correction (CMS-2567) to comport to the existing requirement.

Thank you for bringing this to our attention.

Sincerely,

A handwritten signature in black ink, appearing to read "Lee A. Fleisher". The signature is fluid and cursive, with a long horizontal stroke at the end.

Lee A. Fleisher, MD
Chief Medical Officer and Director
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services

EXHIBIT A



March 16, 2021

Daniel J. Barry
Acting General Counsel
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 713-F
Washington, DC 20201

VIA EMAIL: Good.Guidance@hhs.gov

Re: Petition for Review of CMS State Operations Manual, Appendix A, Regulations and Interpretive Guidelines for Hospitals

To Whom it May Concern:

The Massachusetts Health & Hospital Association (“MHA”) advances the health of individuals and communities by serving as the leading voice for all Massachusetts hospitals, healthcare systems and other care providers to help them provide high quality, cost-effective and accessible healthcare. Through leadership in public advocacy, education, and information, MHA represents and advocates for the collective interests of its members and supports their efforts to provide high quality, cost-effective and accessible care during an era of unprecedented change.

MHA is writing on behalf of one of its member hospitals regarding CMS Transmittal R37SOM dated October 17, 2008, which revised the State Operations Manual, Appendix A, Regulations and Interpretive Guidelines for Hospitals, to reflect amended regulations and survey certification policy issuances concerning Medicare Conditions for Participation for Hospitals at 42 CFR Part 482. In this petition, we request that the Department modify Section A-0057 of Appendix A, because a Department of Health and Human Services (“HHS”) component is using this guidance document to create additional legal obligations beyond what is required by the terms of 42 CFR Part 482.¹ In short, a State Surveyor Agency is interpreting Section A-0057 of Appendix A to prohibit hospitals within a health system from designating the same individual as Chief Executive Officer of each of its hospitals. Notably, the applicable regulation does not require such a prohibition. Furthermore, this interpretation directly contradicts the Center for Medicare & Medicaid Services’ (“CMS’s”) position on this issue, articulated in hospital surveyor training materials.

¹ See Dept. of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78770, 78786 (Dec. 7, 2020) (codifying good guidance practices in regulation, including procedure to petition for review of guidance) (hereinafter referred to as “Good Guidance Final Rule” or “Final Rule”).

BACKGROUND

According to CMS regulations governing hospital Medicare conditions of participation, a hospital must have a “governing body that is legally responsible for the conduct of the hospital.”² The regulations also provide that “[t]he governing body must appoint a chief executive officer who is responsible for managing the hospital.”³ Notably, these regulations do not discuss whether the same individual can serve as the chief executive officer (“CEO”) of two hospitals within one health system, although we believe such a scenario complies with the regulatory language, as each hospital would still have one CEO “who is responsible for managing the hospital.”

In Appendix A of the State Operations Manual (“SOM”), CMS provides additional interpretive guidance on certain regulations for surveys conducted to ensure hospital compliance with the Medicare conditions of participation.⁴ In Section A-0057, CMS outlines interpretive guidelines and survey procedures for § 482.12(b)’s CEO standard. Specifically, CMS directs surveyors to:

- verify that the hospital has only one chief executive officer for the entire hospital;
- verify that the governing body has appointed the chief executive officer; and
- verify that the chief executive officer is responsible for managing the entire hospital.⁵

These survey procedures, like the regulations mentioned above, do not discuss whether an individual can serve as the CEO of two hospitals within one health system. Arguably, these survey procedures provide additional context to support the proposition that the same individual can indeed serve as the CEO for multiple hospitals.

The first procedure establishes two conditions: 1) a particular hospital can only have one CEO; and 2) that individual must be CEO of the entire hospital. The second procedure simply indicates that the hospital’s CEO must be appointed by the governing body, and not by any other entity or individual. The last procedure establishes the required scope of a CEO’s duties. Nothing in these three points indicates a policy decision that excludes an arrangement under which the same individual is CEO of more than one hospital within a system. If that were indeed CMS’s position, these survey procedures would have been a perfect opportunity for CMS to delineate its intention to prohibit this practice. However, when presented with this opportunity, CMS declined to make such intention clear.

In fact, CMS appears to have adopted the opposite approach in related agency materials. For example, CMS created the Hospital Basic Training (“HBT”) online course to provide surveyors “with the basic knowledge and skills needed to survey hospitals for compliance with the Medicare Hospital Conditions of Participation.”⁶ In the training module on hospital CEOs, CMS restates its interpretive guidelines on this issue, and also directs surveyors to locate the board minutes that

² 42 C.F.R. § 482.12.

³ *Id.* at 482.12(b).

⁴ State Operations Manual, Appendix A, Regulations and Interpretive Guidelines for Hospitals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

⁵ SOM, Appendix A, Interpretive Guidelines § 482.12(b).

⁶ See https://qsep.cms.gov/pubs/EPlayer.aspx?cid=0CMSHOSPLBPT1_CEU_ONL&sco=7a4d4b5c-6e7f-e611-b12d-90e2ba614aa5&sv=0

contain the governing body's CEO determination; and ask for documentation that the CEO was granted and has authority over the entire hospital.⁷

The training module also provides an "exercise question" that directly addresses the CEO issue. The question asks whether the following hypothetical would present compliance issues: "A hospital system owns three separately certified hospitals and its governing body, which is a system governing body, has appointed one individual to be Chief Executive Officer (CEO) for all three hospitals." CMS provides an answer that indicates such an arrangement would not be problematic: "Each hospital has a CEO; *it does not matter that the CEO is also the CEO of other hospitals, as long as he or she fulfills all the responsibilities of a CEO at each of the hospitals.*"

STATE SURVEY

In the fall of 2017, one of our member hospitals received a letter from CMS's Northeast Division of Survey & Certification indicating that a survey conducted by the Massachusetts Department of Public Health/Division of Health Care Facility Licensure ("State Survey Agency") found that the facility was not in substantial compliance with 42 C.F.R. § 482.12. In the Form CMS-2567, Statement of Deficiencies, the State Survey Agency alleged that our member hospital, which is part of a larger health system, was in violation of Section A-0057 of Appendix A because "[t]he Governing Body failed to appoint one Chief Executive Officer (CEO) who was responsible for managing *only* Hospital A in its entirety." The surveyor further noted, "The Health Care System Organizational Chart did not indicate a Chief Executive Officer *responsible only for managing Hospital A* in its entirety and did not indicate a Chief Executive Officer *responsible only for managing Hospital B* in its entirety."

At the time, as is customary for many health systems throughout the country, the same individual was designated and served as the CEO of the two hospitals within the system. As a result of the survey findings, our member hospital implemented a Plan of Correction ("PoC"), which adjusted the hospital's organizational structure to remedy what the State Survey Agency alleged to be violations of the applicable regulations. In particular, it certified that "the Governing Board of Hospital A will appoint one Chief Executive Officer who is responsible for managing Hospital A in its entirety, and who reports to the Governing Board."

In January 2018, our member hospital received a letter from CMS's Northeast Division of Survey & Certification stating that a follow-up survey conducted by the State Survey Agency found that the violations were remedied and the hospital was in compliance with the Medicare Conditions of Participation for Hospitals at 42 C.F.R. Part 482.

HHS COMPONENT CREATING ADDITIONAL LEGAL OBLIGATIONS

Our member hospital has maintained compliance with the PoC by continuing to designate one individual as the CEO of only that hospital. The sister hospital within the system has done the same. However, we believe the State Survey Agency, which conducted the relevant survey at

⁷ See HBT1, Module 8, Lesson 2, Topic 3: Chief Executive Officer.

CMS's direction and thus operated as a component of HHS,⁸ used a guidance document to create additional legal obligations beyond what is required by the terms of the applicable regulations. Specifically, the State Survey Agency incorrectly interpreted Section A-0057 of Appendix A of the SOM to prohibit arrangements under which the same individual serves as the CEO of multiple hospitals within a system. This interpretation required our member hospital to implement a PoC that made certain changes to its organizational structure "beyond what is required by the terms of" 42 C.F.R. § 482.12. What's more, the state surveyor's interpretation directly contradicts CMS's training module, which is, to our knowledge, the only time CMS has expressed its position on this particular issue.

It should be noted that Appendix A of the SOM is a "guidance document" under the Good Guidance Final Rule. HHS defined "guidance document" as any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation."⁹ That Appendix A of the SOM is an "internal agency document" addressed to hospital surveyors does not change the analysis. In the Final Rule, HHS noted that internal agency documents can "constitute guidance documents if they are designed to guide the conduct not just of agency officials, but also regulated parties, and [reiterated] that whether a document is properly considered a "guidance document" under this rule is a functional test."¹⁰ Applying HHS's "functional test" here, although Appendix A is addressed to hospital surveyors, hospitals often rely on the interpretive guidelines and survey procedures outlined in Appendix A to guide future conduct, policies and procedures.

Appendix A would still qualify as a guidance document under the Final Rule if HHS alternatively deems it to be a document "issued by HHS to agency contractors," and not an "internal agency document." In the Final Rule, HHS clarifies that "[d]ocuments issued by HHS to agency contractors can be guidance documents if they include interpretive rules or policies that are of general applicability...."¹¹ As described above, Appendix A provides interpretive guidelines on several regulations that govern the conduct of hospital providers.

CONCLUSION

In sum, we believe Section A-0057 of Appendix A of the SOM is being used by an HHS component to create additional legal obligations beyond what is required by the terms of the applicable regulation. 42 C.F.R. § 482.12(b) does not in any way address the question of whether the same individual can serve as the CEO of multiple hospitals within a system. For that matter, neither does Section A-0057 of Appendix A.

⁸ According to Section 1864 of the Social Security Act, State Survey Agencies may conduct at CMS's direction, surveys of deemed status providers on a selective sampling basis, in response to a substantial allegation of noncompliance, or when CMS determines a full survey is required after a substantial allegation survey identifies substantial noncompliance. CMS uses such surveys as a means of validating the accrediting organization's survey and accreditation process.

⁹ 85 Fed. Reg. at 78785.

¹⁰ *Id.* at 78772.

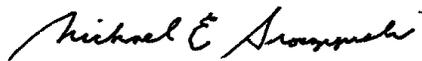
¹¹ *Id.* at 78773.

Nonetheless, the State Survey Agency misinterpreted Section A-0057's provision which states that the survey must "verify that the hospital has only one chief executive officer for the entire hospital." to mean that one individual cannot serve as CEO of multiple hospitals. A literal reading of this provision suggests CMS's actual concern is with arrangements under which *one* hospital has *multiple* CEOs, and the consequent delegation of authority and responsibilities that can arise under such an arrangement.

Given the above, we seek a determination from HHS that Section A-0057 of Appendix A is being misinterpreted in a way that creates additional legal obligations beyond what is required by the terms of § 482.12. We also respectfully request a prompt modification of A-0057, to better align with industry practice, and CMS's own statement of policy expressed in its surveyor training modules: "it does not matter that the CEO is also the CEO of other hospitals, as long as he or she fulfills all the responsibilities of a CEO at each of the hospitals."

We respectfully request that HHS act expeditiously to review the guidance document in question and issue a decision on our petition.

Sincerely,



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