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REPORT TO THE CONGRESS

Physician Supervision Requirements in Critical Access Hospitals and Small Rural Hospitals

MEDPAC Medicare Payment Advisory Commission

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Executive summary

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The 21st Century Cures Act of 2016 (Section 16004) instructed the Centers for Medicare & Medicaid Services (CMS) not to enforce physician supervision requirements for outpatient therapeutic services in critical access hospitals (CAHs) and small rural hospitals through 2016. The Act also mandated that the Medicare Payment Advisory Commission report to the Congress about the effects of extension of the enforcement instruction on Medicare beneficiaries' access to and quality of care as well as its economic impact on the affected hospitals.

In 2009, prior to the passage of the Cures Act, CMS had clarified the agency's then-current policy that a physician must be immediately available to furnish assistance and direction throughout the performance of an outpatient therapeutic procedure (i.e., direct supervision). CAH and rural hospital representatives subsequently expressed concerns that, because they have difficulty recruiting physicians to practice in rural areas, the direct supervision requirement may limit beneficiary access to care in their hospitals. In response to these concerns, CMS instructed all Medicare administrative contractors not to evaluate or enforce the supervision requirements for therapeutic services in CAHs and rural hospitals with 100 or fewer beds from 2010 to 2013. The Congress extended this instruction not to enforce supervision requirements from 2013 to 2016. CMS is continuing nonenforcement in 2018 and 2019. There is currently a legal and regulatory gap in the enforcement instruction for 2017.

Because no databases exist to indicate whether and how hospitals meet physician supervision requirements, we based our analysis on interviews. We spoke with staff from CMS, hospital association representatives, and the leadership of CAHs in multiple states to understand whether the direct supervision requirements 1) have an economic impact on hospitals and their staffing needs and 2) affect Medicare beneficiaries' access to and quality of care. The hospital representatives most frequently discussed the supervision of chemotherapy infusion and cardiac rehabilitation, which are common therapeutic services that both require direct supervision. We did not hear from the CAHs that the supervision requirements cause a significant economic burden. The CAHs have put in place processes with current staff to offer what they believe to be the appropriate supervision (e.g., using family physicians in the same building as a chemotherapy suite), but they are unclear whether these processes satisfy the supervision requirements. The representatives we spoke with indicated that CAHs face challenges recruiting physicians to staff their hospitals, but, in contrast to hospital association statements, they said that the direct supervision requirements for outpatient therapeutic services are not limiting the types of services they provide. If the hospital can contract with the appropriate specialists and has the necessary volume of patients, it offers its patients access to these services using processes hospital staff believe meet the supervision requirements, or it may limit the hours or days the services are offered based on the specialist's availability. In our conversations with CMS officials, they noted that there have been no quality of care (e.g., patient safety) concerns raised to them about hospitals, whether rural or urban, using inappropriate physician supervision for outpatient therapeutic services.

One of the Commission's guiding principles is that expectations for quality of care in rural and urban areas should be equal for nonemergency services that rural providers choose to deliver. That is, if a provider has made a discretionary decision to provide a service, that provider should be held to a common standard of quality for that service (e.g., physician supervision standards), whether it is provided in an urban or rural location. The Commission also believes that determining the supervision needed for these discretionary services is a clinical decision about the appropriate level of care needed to safely deliver the service to the beneficiary.

We understand that CMS's general policy is to initially treat all hospital outpatient therapeutic services as requiring direct supervision and then use input from an advisory panel to determine when a level of supervision other than direct may be appropriate. The Commission believes that CMS should use clinical judgment regarding the patient's safety when deciding the most appropriate supervision level for outpatient therapeutic services and that its clinical decision should apply to both urban and rural hospitals. CMS could also consider whether using telehealth (e.g., video communication) during the delivery of therapeutic services is clinically appropriate for specific services. The Commission urges CMS to further clarify how the agency defines "immediately available" and "interruptible" in the direct supervision requirement for outpatient therapeutic services. In so doing, CMS should provide a maximum time required for a physician to arrive on site if needed during the therapeutic service. ■

Physician supervision requirements in critical access hospitals and small rural hospitals

Mandate: Section 16004 of the 21st Century Cures Act

(a) EXTENSION OF ENFORCEMENT INSTRUCTION ON SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL HOSPITALS THROUGH 2016. —Section 1 of Public Law 113–198, as amended by section 1 of Public Law 114–112, is amended— (1) in the heading, by striking ''2014 AND 2015'' and inserting ''2016''; and (2) by striking ''and 2015'' and inserting '', 2015, and 2016.''

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission (established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6)) shall submit to Congress a report analyzing the effect of the extension of the enforcement instruction under section 1 of Public Law 113–198, as amended by section 1 of Public Law 114–112 and subsection (a) of this section, on the access to health care by Medicare beneficiaries, on the economic impact and the impact upon hospital staffing needs, and on the quality of health care furnished to such beneficiaries. ■

Background

The Commission's mandate

The 21st Century Cures Act (Section 16004, Continuing Access to Hospitals Act of 2016) instructed the Centers for Medicare & Medicaid Services (CMS) not to enforce physician supervision requirements for outpatient therapeutic services in critical access hospitals (CAHs) and small rural hospitals through 2016.[1] The Act also mandated that, by December 13, 2017, the Commission submit to the Congress a report analyzing the effects of the enforcement instruction on Medicare beneficiaries' access to and quality of care and the economic impact on hospitals (see text box that includes the relevant sections).

To meet our mandate, we based our analysis on interviews because no databases exist to indicate whether and how hospitals meet physician supervision requirements. We discussed the issue with staff from CMS, hospital association representatives, and the leadership of CAHs in multiple states. We also researched the regulatory and legislative history of physician supervision requirements for hospital outpatient therapeutic services. This report presents our analysis and the Commission's position on physician supervision requirements.

History of physician supervision requirements and their enforcement

Medicare beneficiaries receive a wide range of therapeutic services in hospital outpatient settings, varying in complexity from immunization administration to chemotherapy and radiation oncology. As a condition of Medicare payment for outpatient services, hospitals must furnish

these services in accordance with applicable state laws, including state licensure and permitted scope of practice for physicians and other clinicians. Also as a condition of Medicare payment, the billing physician or approved nonphysician provider (NPP) (such as a physician assistant, nurse practitioner, or clinical psychologist) must be involved in the care (e.g., writing orders and providing appropriate supervision of services).

Prior to the passage of the Cures Act, during the 2009 payment system rulemaking process for Medicare hospital outpatient services and ambulatory surgical centers (ASCs), CMS restated and clarified the agency's then-current policy, in place since 2001, that outpatient therapeutic services for Medicare beneficiaries delivered in a hospital must be directly supervised by an appropriate physician or NPP.[2] (CMS does not indicate the specialty of the physician or NPP who can provide the supervision.) Over the years, CMS has added flexibility to and partially clarified the definition of direct supervision—for example, adding that emergency department (ED) physicians can provide direct supervision if they are "interruptible" (see text box defining levels of supervision). (The industry is concerned. though, that—since CMS has held that the supervision policy has been in place since 2001—the entire hospital community (both rural and urban) is open to potential recoupments and whistle-blowers who can claim that a hospital did not have appropriate supervision requirements in place back to 2001 (American Hospital Association 2017).)

In 2012, CMS implemented an independent review process, through the Hospital Outpatient Payment (HOP) Panel, to determine whether a level of supervision other than direct (e.g., general supervision or nonsurgical extended duration therapeutic services (NSEDTS) supervision) offers appropriate patient safety and quality during the delivery of the service. The HOP Panel consists of up to 15 members—selected by the Secretary of Health and Human Services or the CMS Administrator—from, for example, the fields of hospital payment systems and provider billing and accounting systems. Panel members are full-time employees of hospitals, hospital systems, or other Medicare providers. Currently, 10 of the panel members are clinicians. For supervision deliberations, the HOP Panel must also include members who represent the interests of CAHs. Two of the panel members are currently employed at a CAH. A federal official designated by the Secretary of Health and Human Services or the CMS Administrator serves as the chair of the panel, which meets once a year. During the meeting, the panel can review supervisory-level evaluation requests along with clinical justifications submitted to CMS by stakeholders, usually hospitals.[3] The panel makes recommendations to inform preliminary agency decisions, but CMS makes the final decision on the supervision level appropriate for each service (Centers for Medicare & Medicaid Services 2017a). Based on the panel's input since 2012, CMS has reduced the level of supervision for about 50 services from direct to general supervision (American Hospital Association 2017).

Hospital associations have expressed concern to CMS that small rural hospitals and CAHs have insufficient staff available to furnish direct supervision and that they have difficulty recruiting physicians and NPPs to practice in rural areas. In response to these concerns, CMS instructed all Medicare administrative contractors not to evaluate or enforce the supervision requirements for therapeutic services in CAHs and rural hospitals with 100 or fewer beds during 2010. CMS extended, through regulation, this notice of nonenforcement as an interim measure for 2011 and again for 2012 and 2013. The Congress has legislatively (Pub. L. 113–198 and Pub. L.

Definitions of physician supervision levels

The Centers for Medicare & Medicaid Services (CMS) has defined four levels of physician supervision and regulates what type of supervision is required for each type of service.

General supervision: The procedure is furnished under the physician's or nonphysician provider's (NPP's) overall direction and control, but his or her presence is not required during the performance of the procedure (e.g., blood transfusion service).

Direct supervision: The physician or NPP must be immediately available to furnish assistance and direction throughout the performance of the procedure (e.g., intravenous chemotherapy infusion), but he or she does not have to be present in the room. Through rulemaking, CMS has clarified that *immediately available* means the physician must have a physical presence (not "on call"), though CMS has not defined a distance or time interval in which the physician must be available. Physicians must also be "interruptible" if concurrently engaged in other activities. Hospitalists or emergency department physicians can provide direct supervision if they are "interruptible," licensed, and have hospital privileges to furnish the services.

Nonsurgical extended duration therapeutic services (NSEDTS) supervision: A hybrid of direct and general supervision, NSEDTS (services such as therapeutic/prophylactic injections and infusions) require direct supervision initially, with potential transition to general supervision at the discretion of the supervising practitioner.

Personal supervision: The physician or NPP must be in attendance in the room during the performance of the procedure (e.g., ultrasonic guidance for administration of radiation therapy).

Medicare requires direct supervision for all hospital outpatient therapeutic services unless CMS assigns another appropriate supervision level for an individual service (Centers for Medicare & Medicaid Services 2015, Centers for Medicare & Medicaid Services 2014, Centers for Medicare & Medicaid Services 2013). ■

114–112) extended nonenforcement of the direct supervision of hospital outpatient therapeutic services since December 31, 2013. The latest legislative action (Pub. L. 114–255) extended nonenforcement until December 31, 2016. In its final rule for the 2018 outpatient prospective payment system (OPPS), CMS stated that it would continue not to enforce the direct supervision requirement in CAHs and small rural hospitals during 2018 and 2019 (Centers for Medicare & Medicaid Services 2017b). There is currently a legal and regulatory gap in the enforcement instruction for 2017. CMS's rationale is that the extension will give CAHs and small rural hospitals more time to comply with the supervision requirements for outpatient therapeutic services. However, we believe it is unlikely that the additional time is going to solve rural hospital physician recruitment issues. CMS has also noted that the extension would give all

parties time to submit specific services to be evaluated by the HOP Panel for a recommended change in the supervision level. However, the HOP Panel has already been reviewing appropriate supervision levels for services over the past six years.

Findings

We spoke with staff from CMS, hospital association representatives, and the leadership of CAHs in multiple states to understand whether direct supervision requirements affect Medicare beneficiaries' access to and quality of care and to evaluate the requirements' economic impact on hospitals and their staffing needs. The hospital representatives most frequently discussed how they provide chemotherapy and cardiac rehabilitation (CR) services, which are common therapeutic services that both require direct supervision. (Note that CR specifically requires a physician—not other advanced practice clinicians—to supervise.)[4,5]

Access to care

Though the CAH representatives we spoke with indicated that they face challenges recruiting physicians to staff their hospitals, they did not say that the direct supervision requirements for outpatient therapeutic services are limiting the types of services they provide. If the hospital can work with the appropriate specialists (i.e., oncologists and cardiologists) and has the necessary volume of patients, it offers its patients chemotherapy infusions and CR. CAHs have implemented various processes that they believe address CMS's direct supervision requirements and offer appropriate access to care. For example, some CAHs say they believe their ED physicians or family physicians located in the building or nearby meet the direct supervision requirement. One CAH schedules its few chemotherapy infusion appointments on the one to two days of the week that the oncologist is present because of the specialist's preference. Depending on physician availability and patient volume, some CAHs offer CR services three days a week while others offer them Monday through Friday.

Quality of care

All of the CAH representatives explained that they put quality of care and patient safety first when deciding whether to offer therapeutic services to patients. For example, one hospital representative said that the hospital's oncologist refers high-acuity patients to begin chemotherapy in a large hospital, one that is more adept at handling complications, and if no complications arise with the initial treatment, then the patients can receive subsequent treatments at the local CAH.

In our conversations with CMS personnel, they noted that no patient safety concerns have been raised about hospitals, rural or urban, using inappropriate physician supervision for outpatient therapeutic services. CMS also noted that there is currently no way to monitor this requirement through administrative data (e.g., claims), so it is challenging to enforce. The Medicare program would likely learn of any concerns about patient safety due to inappropriate supervision through a whistle-blower.

Economic impact on hospitals and their staffing needs

In the 2018 final rulemaking for the OPPS, CMS described feedback from stakeholders that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision. The stakeholders also commented that it is particularly difficult to provide direct supervision for critical specialty services, such as radiation oncology, that cannot be directly supervised by an ED physician because of the volume of emergency patients or lack of specialty expertise. However, CAH representatives we spoke with did not mention that the supervision requirements would cause a significant economic burden; they also did not indicate that they lack sufficient staff to furnish direct supervision for therapeutic services. Rather, representatives described processes the CAHs have put in place with current staff to offer what they believe to be the appropriate level of supervision.

For chemotherapy and CR, hospital spokespeople reported that they are using ED or family practice physicians or NPPs in the same building or on campus to address physician supervision requirements if an oncologist or cardiologist is not available. We heard that some hospitals have specifically included supervision of outpatient chemotherapy, if an oncologist is not present, in ED physician contracts. (These hospitals' administrators had to work with the ED and family physicians to explain their scope of practice and responsibility for care during these treatments (e.g., responding during an adverse event).) One CAH representative explained that, during CR, a cardiologist is personally present for some aspects of the care—for example, during a stress test—and that a nurse provides much of the exercise supervision and education components of the program, with an ED or family physician always available in a short amount of time. Another representative explained that the oncologist is available for chemotherapy patients one day a week, but the other days of the week, the oncology-certified nurse who runs the chemotherapy suite can call on the ED physician if a patient care emergency arises. The oncologist is also in touch over the phone daily. One hospital, in its newly constructed building, put its family medicine practice across the hall from the outpatient chemotherapy suite to meet the direct supervision requirement if an oncologist is not available. In general, CAHs have been able to meet the supervision requirements, as they interpret them, with existing staff. Therefore, the economic impact of the supervision requirements appears to be limited.

Summary

The hospital industry has urged the Congress and CMS to eliminate the enforcement of CMS's direct supervision requirements for CAHs and small rural hospitals. They note that the shortage of medical professionals in rural areas may force small rural hospitals and CAHs to limit their hours of operation or cut services to comply with the supervision requirements, which could result in reduced access to outpatient care. In contrast to the hospital association's statements, CAH representatives we spoke with did not indicate that addressing the direct supervision requirements would cause them to significantly limit their services. We also did not hear requests to permanently extend the nonenforcement moratorium for direct supervision. We did hear that the CAHs have implemented processes to address supervision requirements, though they are sometimes unclear about whether those processes (such as their use of ED and family physicians for coverage) satisfy the supervision requirements.

The Commission's position on physician supervision requirements

In its June 2012 report to the Congress, the Commission defined a set of principles designed to guide expectations and policies with respect to rural patients' access to care, rural providers' quality of care, and the Medicare program's payments to rural providers. One principle is that expectations of quality of care in rural and urban areas should be equal for whatever nonemergency services rural providers choose to deliver. That is, if a provider has made a discretionary decision to provide a service, that provider should be held to a common standard of quality for that service (e.g., physician supervision standards), whether it is provided in an urban or rural location (Medicare Payment Advisory Commission 2012).

The Commission also believes that determining the supervision required for these discretionary services is a clinical decision about the level needed to safely deliver the service to the beneficiary. The clinical decision about supervision should take into consideration the complexity of the service, probability of unexpected or adverse patient events, and expectation of rapid clinical changes during the therapeutic service or procedure. Rural hospital spokespeople said that chemotherapy and CR services are the two services for which meeting direct supervision requirements is the most challenging. CMS should continue to gather advice from the HOP Panel, which includes many clinicians and some CAH leadership, on appropriate supervision levels. However, we believe that CMS should use its own clinical judgment regarding patient safety to determine the most appropriate supervision level for these and other therapeutic services, and that their clinical decision should apply to both urban and rural hospitals. CMS could also consider whether using telehealth (e.g., video communication) during the delivery of therapeutic services is clinically appropriate for specific services. CMS may need to seek statutory changes to more broadly implement telehealth, if the agency determines that such technology may help small rural hospitals comply with the applicable supervision requirements.

CMS should present hospitals with physician supervision requirements that are specific and clear but also allow hospitals flexibility in how they meet those requirements. Based on our conversations with rural hospital spokespeople, the Commission believes that hospitals need further clarity from CMS on how the agency defines "immediately available" and "interruptible" in the direct supervision requirement for outpatient therapeutic services. CMS should provide a maximum time required for a physician to arrive on site if needed during the therapeutic service. CMS should also clarify for and emphasize to hospitals that the direct supervision requirements do not specify which type of physician needs to supervise a service. Although particularly relevant for rural hospitals that face physician shortage issues, clarification of the supervision requirements can benefit all hospitals. ■

Endnotes

1 Medicare beneficiaries can receive care in over 1,300 small hospitals called critical access hospitals (CAHs). CAHs are limited to 25 beds and primarily operate in rural areas. They have their own payment method and conditions of participation. CAHs must provide 24-hour emergency services with medical staff either (1) on site, on call, and/or available on site within 30 minutes or (2) available within 60 minutes if certain frontier-area criteria are met.

2 The Commission assumes that any provider used to fill the direct supervision requirement is properly credentialed and privileged.

3 In determining the appropriate supervision level for an outpatient therapeutic service, the panel uses the following evaluation criteria: complexity of the service, acuity of the patients receiving the service, probability of an unexpected or adverse patient event, expectation of rapid clinical changes during the service or procedure, recent changes in technology or practice patterns that affect a procedure's safety, and the clinical context in which the service is delivered.

4 CMS currently requires direct supervision for intravenous chemotherapy infusions. In 2015, the HOP Panel recommended general supervision for the service, but CMS leadership made the final determination of direct supervision because of the potential adverse reactions patients can have during chemotherapy. The HOP Panel has discussed the appropriate level of supervision for chemotherapy several times, and their recommendation has varied over time (e.g., general versus direct supervision) likely because the panel membership changes over time.

5 Medicare Part B covers general or intensive CR programs that include physician-supervised exercise, education, and counseling. Patients must be referred to CR by a doctor, and the beneficiary must have had a defined cardiac event like a heart attack in the last 12 months, coronary artery bypass surgery, or a heart valve replacement. Medicare will cover up to 2 one-hour sessions per day for up to 36 sessions over 36 weeks for general CR and up to 6 one-hour sessions per day for up to 72 sessions over 18 weeks for intensive CR.

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About MedPAC

The Commission

The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105–33) to advise the U.S. Congress on issues affecting the Medicare program. In addition to advising the Congress on payments to health plans participating in the Medicare Advantage program and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

The Commission's 17 members bring diverse expertise in the financing and delivery of health care services. Commissioners are appointed to three-year terms (subject to renewal) by the Comptroller General and serve part time. Appointments are staggered; the terms of five or six Commissioners expire each year. The Commission is supported by an executive director and a staff of analysts, who typically have backgrounds in economics, health policy, and public health.

MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress. In the course of these meetings, Commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties. (Meeting transcripts are available at www.medpac.gov.) Commission members and staff also seek input on Medicare issues through frequent meetings with individuals interested in the program, including staff from congressional committees and the Centers for Medicare & Medicaid Services, health care researchers, health care providers, and beneficiary advocates.

Two reports—issued in March and June each year—are the primary outlets for Commission recommendations. In addition to annual reports and occasional reports on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

The Commission's goal is to achieve a Medicare program that ensures beneficiary access to high-quality care, pays health care providers and health plans in a manner that is fair and rewards efficiency and quality, and spends tax dollars responsibly.

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