U.S. DISTRICT COURT UPHOLDS CMS'S APPLICATION OF THE STATUTORY REQUIREMENT THAT HOSPITALS BE "PRIMARILY ENGAGED" IN PROVIDING SERVICES TO INPATIENTS

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U.S. Health Care Alert

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On January 25, 2018, the U.S. District Court for the Eastern District of Pennsylvania granted summary judgment in favor of the Centers for Medicare & Medicaid Services ("CMS") following an eye hospital's appeal of the agency's denial of its application to enroll in Medicare as a hospital.[1] In doing so, the Court upheld CMS's application of the statutory definition of "hospital," which requires, in relevant part, that the institution in question

> is *primarily engaged* in providing, by or under the supervision of physicians, to *inpatients* (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons . . . [2]

One of the issues before the Court in *Wills v. Burwell* was the lack of regulations or interpretive guidelines regarding CMS's interpretation or enforcement of this definition. In the months leading up to the decision in *Wills v. Burwell*, CMS released a number of survey and certification ("S&C") memos describing (1) the applicable survey procedures for evaluating whether a facility is primarily engaged in providing inpatient services and (2) the factors CMS, state survey agencies, and accrediting organizations will use when assessing whether a facility is primarily engaged in providing services to inpatients.

The Court's decision in Wills v. Burwell and CMS's recently released interpretive guidelines demonstrate not only CMS's interest in enforcement on this issue, but also that courts may uphold CMS's application and interpretation of the statutory definition. In light of this, we recommend that hospitals—particularly specialty hospitals, so-called micro hospitals, and other community hospitals with a routinely low inpatient census—conduct evaluations based on the CMS's recently announced factors to determine whether they are at risk of not meeting the criteria to be considered primarily engaged in providing inpatient services. In that regard, enforcement in this area is likely to impact both facilities submitting applications to enroll and be certified as a hospital and existing facilities that are currently enrolled and certified as hospitals.

BACKGROUND

CMS has historically assessed whether facilities are primarily engaged in providing inpatient services on a case-by-case basis.[3] In 2008, CMS issued a S&C memo related to off-campus provider-based departments indicating that, while not dispositive, it would look at whether the proportion of inpatient beds to all other beds was 51% or greater and would consider other factors in addition to bed ratio upon request.[4] There have also been cases and administrative decisions upholding CMS's denial or termination of facilities' enrollments as hospitals on the basis that the facilities did not meet the "primarily engaged" requirement.[5]

WILLS V. BURWELL

In *Wills v. Burwell*, the appellant, The Wills Eye Trust, doing business as Wills Eye Hospital ("Wills Eye"), was a facility specializing in ophthalmology. In 2002, Wills Eye began operating a facility that enrolled in Medicare as an ambulatory surgical center ("ASC").[6] In 2011, Wills Eye renovated the ASC facility and added four inpatients beds.[7] In 2013, Wills Eye received a state license to operate the renovated facility as a hospital and applied for Medicare enrollment.[8] Upon survey, the state survey agency recommended the renovated facility for Medicare enrollment as a hospital.[9] Nonetheless, CMS denied Wills Eye's application because the renovated facility was not "primarily engaged in providing inpatient services."[10]

In assessing whether the renovated facility met the statutory definition of a hospital, CMS generally applied a test based on its comparative inpatient and outpatient volume, but it did not limit its consideration to any single factor.[11] Instead, CMS also considered the history, current operations, staffing, location, and other factors regarding the Wills Eye facility.[12] Additionally, CMS noted that Wills Eye did not attempt to show a greater role for inpatient services following its renovation by proffering any contrary evidence as to the facility's long-standing focus on ASC services.[13] In upholding CMS's determination, the Court held, in relevant part, that:

- CMS's administrative decision to deny Wills Eye's application was based on substantial evidence and was not arbitrary or capricious;[14]
- CMS's interpretation of the statutory definition of a "hospital," which included the comparative volume assessment as well as other factors, was not substantive and consequently did not implicate the notice and comment procedures under the Administrative Procedure Act[15] or the Social Security Act;[16]
- CMS's decision to deny Wills Eye's application to enroll as a hospital was not done in a discriminatory manner in violation of the Equal Protection Clause because the record supported that CMS had a rational basis, supported by substantial evidence, for doing so; and
- Wills Eye was provided fair notice of CMS's interpretation of the statutory definition of a "hospital" through publicly available statements made by CMS officials and DAB decisions.[17]

NEW INTERPRETIVE GUIDELINES

Preceding the decision in *Wills v. Burwell*, on September 6, 2017, CMS released an S&C memo adding new

interpretive guidelines to Appendix A of the State Operations Manual.[18] CMS then issued two revised memos to clarify certain aspects of the new interpretive guidelines. According to an informal CMS educational event,[19] the impetus for the new guidance includes:

- Several facility denials of participation in Medicare as a hospital
- Micro hospitals
- ASCs trying to enroll as hospitals
- Section 603 of the Bipartisan Budget Act of 2015 (also known as the site-neutral payment rule)
- Small hospitals with a disproportionate number of off-campus emergency departments ("EDs")
- "Specialty" hospitals, such as emergency or surgical hospitals
- State licensing criteria for hospitals that are not the same as the CMS hospital definition

At least two inpatients at the time of survey

According to the interpretive guidelines, surveyors must observe the actual provision of care at the time of the survey. The hospital must have at least two inpatients for a survey to be conducted, although CMS notes this is merely a starting point and is not necessarily determinative of whether the hospital is "primarily engaged" in accordance with the statutory definition. If a facility does not have at least two inpatients at the time of the survey, a survey will not be conducted. Instead, CMS instructs the surveyors to perform an initial review of the facility's admission data for the prior 12-month period while on site to confirm that the facility had an average daily census ("ADC") of at least two and an average length of stay ("ALOS") of at least two midnights over the past 12 months. The facility's ADC is generally calculated by adding the midnight daily census for each day of the 12-month period and dividing that sum by the total number of days in the year. The facility's ALOS is calculated by dividing the total number of inpatient hospital days (day of admission to day of discharge) by the total number of discharges in the facility over 12 months.[20]

If a facility's ADC and ALOS are two or more, the guidelines indicate that a second survey will be attempted at a later date. If a facility's ADC and ALOS are less than two, CMS indicates that the facility is most likely not primarily engaged in providing care to inpatients, but the surveyor is required to collect additional information from the facility, notify the CMS Regional Office of its findings, and make an independent recommendation as to whether a second survey should be attempted. The CMS Regional Office then makes a determination regarding whether a second survey will be conducted within seven working days.

Other factors

According to the interpretive guidelines, in determining whether to permit a second survey or, instead, recommend denial of an initial application or termination of a current provider agreement, the CMS Regional Office will consider a number of factors, although CMS reiterated its historical position that determinations will not be based on a single factor:

- The number of provider-based off-campus EDs. An unusually large number of off-campus EDs may suggest that a facility is not primarily engaged in inpatient care and is instead primarily engaged in providing outpatient emergency services.
- The number of inpatient beds in relation to the size of the facility and services offered. For example, a facility with four inpatient beds and that has six to eight operating rooms, 20 ED bays, and a 10-bed ambulatory surgery outpatient department is most likely not primarily engaged in inpatient care.
- The volume of outpatient surgical procedures compared to inpatient surgical procedures.
- If the facility considers itself to be a "surgical" hospital, are procedures mostly outpatient?
- Does the information indicate that surgeries are routinely scheduled early in the week, and does it appear this admission pattern results in all or most patients being discharged prior to the weekend (for example does the facility routinely operate in a manner in which its designated "inpatient beds" are not in use on weekends)?
- Patterns and trends in the ADC by the day of the week. For example, does the ADC consistently drop to zero on Saturdays and Sundays (therefore suggesting that the facility is not consistently and primarily engaged in providing care to inpatients)?
- Staffing Patterns. A review of staffing schedules should demonstrate that nurses, pharmacists, physicians, etc. are scheduled to work to support 24/7 inpatient care versus staffing patterns for the support of outpatient operations.
- How does the facility advertise itself to the community? Is it advertised as a "specialty" hospital or "emergency" hospital? Does the name of the facility include terms like "clinic" or "center" as opposed to "hospital"?

CONCLUSION

The *Wills v. Burwell* decision upholding CMS's application of the statutory definition of a "hospital" requiring that the facility be primarily engaged in providing services to inpatients and CMS's recent interpretive guidelines highlights this as an area of increased scrutiny. Facilities seeking to enroll in Medicare as a hospital, as well as existing hospitals, should be aware of this guidance, assess whether they are at risk of not meeting the statutory definition of a hospital, and what options they may have if that is the case.

Notes

[1] *See Trust under the Will of James Wills v. Burwell*, Civ. No. 16-6615, 2018 WL 558469 (E.D.Pa. Jan. 25, 2018) available at http://www.paed.uscourts.gov/documents/opinions/18D0051P.pdf.
[2] *See* 42 U.S.C. § 1395x(e)(1) (emphasis added).
[3] *See* HHS, *Strategic Plan Regarding Physician Investment in Specialty Hospitals Section 5006 of the Deficit Reduction Act Interim Report*, (May 9, 2006) *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/specialty_hospital_issues.html.
[4] CMS, *Survey & Certification Memorandum* (S&C Memo: 08-08)(Jan. 11, 2008) *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-

Memos-to-States-and-Regions-Items/CMS1207239.html?DLPage=1&DLEntries=10&DLSort=3&DLSortDir=ascending.
[5] *See* Kearney Regional Medical Center v. HHS, 2016 WL 6993741 (D. Neb. Nov. 29, 2016) (Court applied the Chevron Doctrine in affirming the Health and Human Service's Departmental Appeals Board ("DAB") decision and upholding CMS's denial of a facility's initial application to enroll in Medicare as a hospital where the facility had provided some care to inpatients but where it was not providing services to inpatients at the time of the accreditation survey for deemed status); *see also* Freedom Pain Hospital v. CMS, DAB Civil Remedies Dec. No. CR4530, 2016 WL 1182176 (Feb. 10, 2016) (administrative law judge ("ALJ") affirmed CMS's termination of a facility's enrollment as a hospital where the facility was not providing services to any inpatients during the course of a four-day validation survey conducted by the state survey agency and where less than 3% of the facility's overall patients were inpatients over a one year-period); *see also* Arizona Surgical Hospital, LLC v. CMS, DAB Decision No. 1890 (Jul. 23, 2003) (DAB upheld the ALJ's grant of summary judgment in favor of CMS's termination of a facility's enrollment as a hospital where the facility was not providing services to any inpatients at the time of its survey and was primarily engaged in functioning as an outpatient surgical facility).
[6] *Wills v. Burwell* at 1.
[7] *Id.*
[8] *Id.*
[9] *Id.* at 2.
[10] *Id.*
[11] *Id.* at 4.
[12] *Id.*
[13] *Id.*
[14] *Id.* at 4.
[15] *Id.* at 5.
[16] *Id.*
[17] *Id.* at 6-9; *citing* Freedom Pain Hosp., DAB No. CR4530 (2016) (H.H.S. Feb. 10, 2016); Kearney Reg'l Med. Ctr., DAB No. 2639 at 12 (2015); Ariz. Surgical Hosp., LLC, DAB No. 1890 at 12 (2003); *also citing* Michael O. Leavitt, Secretary, HHS, *Recommendations Regarding Physician-Owned Hospitals*; *also citing* Mark B. McClellan, MD, Ph.D., Administrator, CMS, *Testimony Before the House Committee on Energy and Commerce Hearing on Specialty Hospitals: Assessing Their Role in the Delivery of Quality Health Care*, May 12, 2005; *also citing* HHS, *Strategic Plan Regarding Physician Investment in Specialty Hospitals Section 5006 of the Deficit Reduction Act Interim Report*, (May 9, 2006); *also citing* CMS, *Survey & Certification Memorandum* (S&C Memo: 08-08) (Jan. 11, 2008).
[18] CMS, *Survey & Certification Memorandum* (S&C Memo: 17-44-Hospitals) (originally released on September 6, 2017 and revised on October 18, 2017 and October 27, 2017), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-17-44.html?DLPage=2&DLEntries=10&DLSort=2&DLSortDir=descending.
[19] CMS, *A Medicare Learning Network® (MLN) Event, CMS Definition of a Hospital Requirements: Primarily Engaged* (November 2, 2017) *available at* https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2017-11-02-Hospital-Call-Presentation.pdf.
[20] CMS clarified that, for facilities open fewer than 12 months at the time of the survey, the surveyor may

calculate the facility's ADC and ALOS based on the number of months the facility has been open, so long as the number of months is not less than three.

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