

PUBLICATION

Recent Changes to Stark Law's Whole Hospital Exception [Ober|Kaler]

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The federal physician self-referral law, or Stark Law, provides a number of exceptions to the law's prohibition of physician referrals of designated health services to an entity in which the physician has an ownership or investment interest. The whole hospital exception to the Stark Law allows for a physician to have an ownership or investment interest in a hospital to which the physician refers designated health services, when the physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in the hospital's subdivision). Social Security Act (SSA) § 1877(d)(3); 42 C.F.R. § 411.355(c)(3). The Affordable Care Act amended the whole hospital exception to impose additional restrictions on physician-owned hospitals (POHs). Section 6001(a)(3) of the ACA restricts a POH from increasing its aggregate physician ownership or investment interests after March 23, 2010. Further, a POH is unable to expand its facility capacity beyond the number of operating rooms, procedure rooms, and beds for which the hospital is licensed on March 23, 2010, unless the Department of Health and Human Services' Secretary grants an exception.

CMS has promulgated regulations establishing a process under which POHs would apply for an exception to the limitation on facility capacity expansion, allowing a hospital that qualifies as either an “applicable hospital” or a “high Medicaid facility” to request an exception once every two years. The eligibility criteria for an applicable hospital include population increases, inpatient Medicaid admissions, bed capacity, and bed occupancy. The eligibility criteria for high Medicaid facilities include: (1) the POH must have higher than average inpatient Medicaid admissions for the three most recent fiscal years for which data is available; and (2) the POH cannot be the sole hospital in the county in which it is located. If CMS grants an exception request, the POH may not increase its beds by more than 200 percent of its baseline number of operating rooms, procedure rooms, and beds for which it was licensed on March 23, 2010. See SSA § 1877(i)(3)(A), (C), (F); 42 C.F.R. § 411.362(c)(1)–(3).

In the [CY 2012 OPPS Final Rule \[PDF\]](#), CMS finalized the requirement that POHs must use filed Medicare hospital cost report data from CMS's Healthcare Cost Report Information System (HCRIS) to determine whether they satisfy an exception to the limitation on facility capacity expansion. POHs seeking eligibility as applicable hospitals must use HCRIS data to determine the criteria for inpatient Medicaid admissions, bed capacity, and bed occupancy. POHs qualifying as high Medicaid facilities must use HCRIS data to determine the inpatient Medicaid admissions criterion. 76 Fed. Reg. 74122, 74518–74520 (Nov. 30, 2011).

Industry input to the 2012 OPPS Final Rule cited the limitations of using HCRIS data to determine whether the POH has satisfied an exception to the restriction on facility capacity expansion. For example, a correctly completed hospital cost report does not include Medicaid managed care admissions or discharges, and as a result, Medicaid managed care admissions and discharges are not available in HCRIS. In addition, a POH may have not filed a cost report for the relevant time period because it was not enrolled as a Medicare provider, and as a result, the POH may not qualify as a high Medicaid facility even though the POH may have treated the requisite number of Medicaid patients. For more discussion about the identified industry limitations, see the [CY 2015 OPPS Proposed Rule \[PDF\]](#). 79 Fed. Reg. 40916, 41053–41054 (July 14, 2014).

In response to the industry-identified HCRIS data limitations, CMS, in the [CY 2015 OPPS Proposed Rule \[PDF\]](#), proposed changes to its policies that would permit POHs to use supplemental data sources in the

expansion request process. First, CMS proposed example “internal data sources” (sources generated, maintained, or under the control of HHS) that POHs may use in the expansion process. Second, CMS proposed that POHs may use “external data sources,” which are generated, maintained, or controlled by a State Medicaid agency. 79 Fed. Reg. 40916, 41054–41055).

CMS also proposed additional modifications to the expansion request process. Importantly, it proposed to modify its then-current interpretation of “the most recent fiscal year for which data are available” from “the most recent year for which HCRIS contains data from at least 6,100 hospitals” to “the year for which the data source(s) used in an expansion exception request contain sufficient data to perform the comparisons required under [42 C.F.R. § 411.362(c)(2) & (3)].” 79 Fed. Reg. at 41055. CMS also proposed to require that the POH requesting an exception provide direct, actual notification to the hospitals whose data are part of the comparisons under 42 C.F.R. § 411.362(c)(2) & (3). Further, CMS proposed to expand the period under which an expansion exception request would be deemed complete, which would follow the Federal Register’s publication that the POH requested an expansion. 79 Fed Reg. at 41055–41056.

CMS addressed the proposals listed above in the [CY 2015 OPPTS Final Rule \[PDF\]](#). CMS did not finalize the proposal permitting POHs to use non-HCRIS internal data. Further, CMS limited the use of external data sources, permitting POHs to use external data sources only to estimate inpatient Medicaid admissions percentages. Thus, POHs may not use external data sources to determine the criteria for average bed capacity and average bed occupancy for applicable hospitals. 79 Fed. Reg. 66770, 66990 (Nov. 10, 2014).

In the CY 2015 OPPTS Final Rule, CMS also adopted separate standards to determine the data sources’ sufficiency for inpatient Medicaid admissions as well as bed capacity and occupancy criteria. For inpatient Medicaid admissions, CMS will consider a data source sufficient when it contains data from the requesting POH and every hospital located in the same county as the requesting POH. This standard applies to both external sources and HCRIS. For bed capacity and occupancy criteria, CMS will consider HCRIS data sufficient for a particular hospital on a state-by-state basis. In addition, a requesting POH must satisfy the bed capacity and bed occupancy for the most recent fiscal year under which HCRIS contains data from a sufficient number of hospitals in the requesting POH’s state. 79 Fed. Reg. at 66993–66994.

Ober|Kaler Comments

CMS has addressed some of the shortcomings in the exception process that in recent years have hampered POHs from further expanding services that have been needed in certain locations. Although it may be too early to tell, the policy changes should enable some hospitals to expand, which will benefit the communities they serve.