

**Changes to Starks's Whole Hospital and Rural Provider Exceptions:  
Reactions to Limitations on Facility Expansion**

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As the healthcare and legal communities await the unfolding of additional rulemakings and regulations implementing the changes mandated by the Patient Protection and Affordable Care Act (PPACA),<sup>1</sup> enacted March 23, 2010, amended by the Health Care and Education Reconciliation Act (HCERA),<sup>2</sup> enacted March 30, 2010, a number of physician-owned hospitals across the country have found themselves in the midst of a compliance struggle. The 2011 Medicare Hospital Outpatient Prospective Payment System Final Rule (Final Rule) released by the Centers for Medicare & Medicaid Services (CMS) on November 2, 2010, revises the Medicare Hospital Outpatient Prospective Payment System to implement certain PPACA provisions and make significant changes to the "whole hospital" and "rural provider" exceptions to the Physician Self-Referral Law (Stark), which impact physician-owned hospitals.<sup>3</sup> In addition to investment and disclosure requirements, this Final Rule imposes limitations and restrictions on physician-owned facility expansion.

Specifically, PPACA prohibits physician-owned hospitals from increasing the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010, or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010 but does have a provider agreement in effect on December 31, 2010, the effective date of that provider agreement.<sup>4</sup> The Secretary of the Department of Health and Human Services (HHS) may grant an exception to a facility wishing to expand pursuant to Section 1877(i)(3) of the Social Security Act, but regulations concerning the exceptions process are not scheduled to be released until January 2012.<sup>5</sup>

In the meantime, a number of the approximately 265 total physician-owned hospitals nationwide affected by this rule are either searching for ways to comply with these new regulations or challenging their implementation through both judicial and legislative channels.<sup>6</sup> Comments and responses accompanying the Final Rule clarified the scope of the limitations on facility expansion, providing that these limitations apply to operating and procedure rooms, regardless of whether or not a State employs a process for licensing such rooms.<sup>7</sup> However, two specific points granted physician-owned hospitals some leeway to expand and still remain within the purview of PPACA's limitations and the Final Rule.

First, the Final Rule freezes the baseline number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of either March 23, 2010, or the effective date of a provider agreement issued between March 23, 2010, and December 31, 2010.<sup>8</sup> However, the number of each type of room or bed may vary, provided the baseline number of operating rooms, procedure rooms, and licensed beds remains the same.<sup>9</sup> This clarification allowed McBride Orthopedic Hospital in Oklahoma City, a seventy-eight bed facility with twenty physician owners to proceed with plans to add two additional operating rooms.<sup>10</sup> After having already spent over \$150,000 in the initial stages of the project, the enactment of PPACA on March 23, 2010 caused McBride executives to abandon the \$2 million expansion.<sup>11</sup> Now, McBride plans to proceed by converting two of its licensed beds to operating rooms.<sup>12</sup> Assuming a physician-owned facility complies with State licensing requirements, alternate uses for existing operating rooms, procedure rooms, and licensed beds remains an option for a facility wishing to make a change in its existing structure regarding the delivery of healthcare services.<sup>13</sup>

Second, CMS utilized a limited definition of "procedure room," instead of adopting a broad definition that could potentially cover any room where a procedure is performed. A procedure room, as defined in 42 CFR §411.362(a), is "a room in which catheterizations, angiographies, angiograms, and endoscopies are performed." The term "procedure room" excepts emergency rooms or departments, exclusive of rooms in which those specific procedures are performed.<sup>14</sup> CMS solicited public comments concerning the inclusion of additional procedures, such as CT and PET scans or other services, in the definition of "procedure room" but declined to expand the definition of procedure rooms in the final rule.<sup>15</sup> CMS stated that it will monitor expansions in procedure rooms and may expand the definition in future rulemakings.<sup>16</sup> Nevertheless, physician-owned facilities retain the ability to expand healthcare service offerings by adding additional rooms for the performance of procedures that are not listed in CMS' definition of "procedure room." Rapid advances in medical technology and increases in modern, less invasive techniques magnify the importance of the limited scope of this definition. The ability to both change the use of rooms and licensed beds within the baseline number and add rooms dedicated to procedures outside of CMS's definition provide existing physician-owned facilities with some tools to expand, keep up with technological advances, and deliver state of the art healthcare services, while still complying with this rulemaking.

Despite these windows of opportunity, some physician-owned facilities still find themselves in a precarious position, having invested significant time and substantial resources to develop completely new facilities or multi-million dollar additions to existing facilities that have essentially been placed on hold by the passage of PPACA and HCERA. Physicians Hospitals of America (PHA) joined Texas Spine & Joint Hospital, Ltd., to file a case against Kathleen Sebelius, Secretary of the Department of Health and Human Services (DHHS), in the United

States District Court for the Eastern District of Texas on June 3, 2010, requesting an injunction and challenging the implementation of Section 6001 of PPACA which prevents physician-owned hospitals from expanding after March 23, 2010.<sup>17</sup> The passage of PPACA halted Texas Spine & Joint Hospital's planned \$27 million expansion to its twenty bed facility.<sup>18</sup>

With the provisional trial date of December 9, 2010, fast approaching, physicians, attorneys, and lawmakers waited to see if Judge Michael Schneider will decide to proceed with this trial date. On November 24, Judge Schneider issued a Notice of Forthcoming Memorandum Opinion and Order Cancelling Trial Setting. PHA and Texas Spine & Joint Hospital presented a plethora of constitutional arguments, ranging from vagueness and arbitrariness to violations of due process and equal protection.<sup>19</sup> Although a Memorandum Opinion and Final Judgment are forthcoming, Judge Schneider made the following findings: (i) The court had jurisdiction to hear the case; (ii) Section 6001 of PPACA has retroactive effect, but does not result in a due process violation or a constitutional taking; (iii) Section 6001 does not deny PHA and Texas Spine & Joint Hospital equal protection under the law; and (iv) Section 6001 is not void for vagueness. The notice provided no additional reasoning for Judge Schneider's findings. The forthcoming Memorandum Opinion and Final Judgment should contain Judge Schneider's reasoning and response to the Motion for Summary Judgment and Motion to Dismiss filed by DHHS. The outcome of this case, in addition to similar pending cases in Virginia and Florida, is particularly important because PPACA includes no severability clause. The case seems likely to proceed to the United States Court of Appeals for the Fifth Circuit pending Judge Schneider's Memorandum Opinion and Final Judgment.

Another \$211 million facility, the Loma Linda University Medical Center-Murietta, in Murietta, CA, gained support from Senator Dianne Feinstein (D-Calif.).<sup>20</sup> Scheduled to open in

March 2011, physicians would hold a 45% ownership interest in this joint venture facility with Loma Linda.<sup>21</sup> Senator Feinstein has supported granting an exception for this particular facility. Such an exception would allow the facility, which has been under construction since 2008, to open under its current ownership structure, despite the requirements of PPACA and HCERA.

PPACA sets forth some details of the exception process to be implemented by the Secretary. The details that exist already show that the exception process is narrow in scope and reserved for limited circumstances. For example, a facility may only request an exception once every two years; is limited to a 100% increase in the number of operating rooms, procedure rooms, and licensed beds; and may only make additions to facilities on the main campus of the hospital.<sup>22</sup> Furthermore, the community in which the hospital requesting the exception is located will be allowed an opportunity to provide input.<sup>23</sup> The scope of the exception is further limited by the kind of physician-owned hospitals that may make a request. Only two types of hospitals will be eligible for the exception process: “high Medicaid facilities” and “applicable hospitals.”<sup>24</sup> These definitions tie the grant of an exception to hospitals with a high Medicaid population, compared to other hospitals in the same geographic area, and to hospitals that fulfill a number of need-based criteria set forth in the statute.<sup>25</sup> As a result, the availability of the exception for those facilities with plans for expansion either already underway upon PPACA’s enactment or in the works may be extremely limited.

Although the complete procedure for requesting an exception currently is not known, regulations concerning the process for requesting an exception are to be released no later than January 1, 2012, and implemented by February 1, 2012.<sup>26</sup> The consequence of this timing gap means that referrals by physician owners or investors that occur after an expansion is completed

but before an exception is granted are prohibited, and any exception made by the Secretary will insulate only those referrals made after the exception is granted.

Changes to the "whole hospital" and rural provider exceptions to Stark adopted in PPACA and HCERA only impact the current expansion plans of a handful of the over 265 total physician-owned hospitals nationwide. However, the long-term ramifications of these requirements pose significant unresolved issues for facilities with physician owners or investors. As cases like *Physician Hospitals of America, et al. v. Sebelius* move through the court system, individual politicians and organizations lobby for exceptions for specific facilities, and a new Congress revisits health reform in the next congressional session, only time will tell what will happen to the development and ownership structure of physician-owned hospitals.

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).
  2. Health Care and Reconciliation Act of 2010, Pub. L. No. 111-152 (2010).
  3. 42 C.F.R. § 411.362 (2010).
  4. *See id.* § 411.362(b)(2).
  5. *Id.*
  6. Christopher Weaver, *Doctor-owned Hospitals Race to Beat Medicare Deadline* (October 28, 2010), *available at* [http://www.physicianhospitals.org/physician\\_general\\_news.php](http://www.physicianhospitals.org/physician_general_news.php).
  7. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), *Hospital Outpatient Prospective Payment System Final Rule with Comment Period* at 1723, CMS-1504-FC (November 2010), *available at* <http://www.cms.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?itemID=CMS1240960&>.
  8. 42 C.F.R. § 411.362(b)(2) (2010).
  9. CMS, *supra* note 7, at 1732-33.

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10. Paula Burkes, *Clarifications Let McBride Move Ahead with Expansion Plans* (November 14, 2010), available at [http://www.newsok.com/article/3514272?searched=McBride&custom\\_click=search](http://www.newsok.com/article/3514272?searched=McBride&custom_click=search).
11. *Id.*
12. *Id.*
13. CMS, *supra* note 7, at 1726, 1734.
14. 42 C.F.R. § 411.362(a) (2010).
15. CMS, *supra* note 7, at 1724.
16. CMS, *supra* note 7, at 1735-36.
17. Dayna Mazzei Worchel, *Spine and Joint Hospital Lawsuit Targets Health Care Law* (September 29, 2010), available at <http://www.allbusiness.com/legal/trial-procedure-judges/15141698-1.html>.
18. Physician Hospitals of America, *PHA and TSJH Provisional Trial Date Set December 9, 2010 in Federal Court in Tyler* (September 30, 2010), available at <http://www.physicianhospitals.org/index.php>.
19. Jessica Zigmond, *Doc-owned Hospital in Texas, PHA Sue HHS Over Reform Rules* (June 7, 2010), available at <http://www.modernphysician.com/article/20100607/MODERNPHYSICIAN/306079978/1120#>.
20. Andis Robexnieks, *A Little Slack: Existing Doc-owned Hospitals Get Break in New Rule* (November 15, 2010), available at <http://www.modernhealthcare.com/article/20101115/MAGAZINE/101119979#>.
21. *Id.*
22. Section 1877(i)(3)(A) of the Social Security Act (42 U.S.C. § 1395nn(i)(3)(B) and (C))(2010).
23. *Id.* at § 1395nn(i)(3)(A)(ii).
24. *Id.* at § 1395nn(i)(3)(A)(i).
25. *Id.* at § 1395nn(i)(3)(E) and (F).
26. *Id.* at § 1395nn(i)(3)(A).