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CMS' 340B Rate Cut Continues to Dampen Hospital Outpatient Expansion Efforts

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Hospitals hoping to benefit from favorable 340B drug pricing when acquiring independent physician practices for conversion to hospital outpatient "provider-based" departments (PBDs) or similarly converting hospital-owned physician practices should, as part of any decision calculus, pay close attention to recent 340B reimbursement rate reductions and monitor pending litigation challenging those reductions. CMS recently promulgated a final rule[1] extending, for CY 2020, its policy limiting 340B drug reimbursement to Average Sales Price minus 22.5 percent for certain off-campus PBDs (i.e., those receiving payment for services under the Medicare Physician Fee Schedule as opposed to the Medicare Hospital Outpatient Prospective Payment System (OPPS) generally applicable to outpatient hospital services).

While on-campus, PBDs receive reimbursement for facility services under OPPS, the Bipartisan Budget Act of 2015, as amended in 2016 by the 21st Century Cures Act and implemented by CMS in regulation,[2] eliminated OPPS reimbursement for *off*-campus PBDs that were not billing under OPPS as of November 2, 2015. (In CMS parlance, these sites are "nonexcepted off-campus PBDs.") However, off-campus PBDs in existence prior to Nov. 2, 2015 are excepted, or grandfathered, from the reduced reimbursement under the Medicare Physician Fee Schedule and instead continue to bill under OPPS.[3] The policy referenced above applies to *nonexcepted* (i.e., non-grandfathered), *off*-campus PBDs.

CMS's 340B reimbursement reduction is, in part, an effort by CMS to counter a recent national trend whereby hospitals purchase oncology chemotherapy infusion practices that have been under increased financial pressure due to dwindling

[1] Calendar Year (CY) 2020 Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule, 84 Fed. Reg. 61142 (Nov. 12, 2019).

[2] 42 C.F.R. §§ 419.22(v) and 419.48.

[3] Even as to these excepted sites, however, CMS has attempted to effectively eliminate OPPS reimbursement for regular clinic visits by capping the applicable OPPS rate at an amount that results in payments approximating that which would have been received at a non-excepted site (*see* 83 Fed. Reg. 58818 (Nov. 21, 2018)). This effort was recently invalidated by the courts (*American Hospital Association et al. v. Azar II*, No. 1:18–cv–02841 (D.D.C. Sept. 17, 2019); such decision was followed by a denial of CMS's motions for reconsideration and for a stay. CMS has announced that it is still deciding whether to appeal the ruling, and that it is nevertheless implementing the originally intended CY2020 reductions per this policy.

IN CASE YOU MISSED IT

Hospital Outpatient Physician "Supervision": CMS's Latest Rule Offers Greater Operational Flexibility But Still Exemplifies the Issue's Complexity

On Nov. 12, Joseph Willey, Lisa Genecov, Laura Keidan Martin and Margaret Donohue published an advisory reviewing the CMS Medicare Rule, which offers greater flexibility to providers by reducing from "direct" to "general" supervision levels for hospital outpatient therapeutic services in 2020.

NAMSS 43rd Educational Conference & Exhibition

Michael Callahan presented "Achieving a Just Culture Approach to the Medical Staff and APPs" session at the NAMSS Educational Conference & Exhibition on Oct. 19.

Social Media Posts Cost Dental Practice $10,000

Megan Hardiman and Cheryl Camin Murray published an advisory on Oct. 10, reviewing a resolution agreement between a dental practice and the OCR after the practice's disclosure of patients' PHI via social media.

Court Invalidates Latest CMS Effort to Reduce Reimbursement at Off-Campus Hospital Outpatient Departments

On Oct. 4, Joseph Willey and Sharon Kantrowitz authored an advisory examining Medicare's move towards "site neutrality," subsequently eliminating payment of different reimbursement levels.

reimbursement. The new hospital owners are able to boost revenue of such practices by taking advantage of 340B reimbursement once such practices become PBDs, which historically has yielded these converted practices larger profit margins compared to the margins previously earned as independent practices. A comment in the preamble to the CY 2019 Final Rule described the phenomenon as follows:

> [T]he opportunity for 340B-participating hospitals to get substantial revenue from cancer drugs has created financial incentives for hospitals to expand oncology services, notably through the acquisition of independent community oncology practices. Furthermore … when these facilities purchased by 340B-participating entities become off-campus PBDs, they also become eligible for 340B Program discounts, thus "further fueling the program's staggering growth." (83 Fed. Reg. 59018)

CMS first announced its current 340B reimbursement policy for nonexcepted off-campus PBDs in the CY 2019 OPPS Final Rule.[4] CMS's goal was to reduce Medicare reimbursement for drugs purchased under the 340B program at those sites from the previously applicable rate of Average Sales Price plus 6% to an amount that approximated the acquisition cost of the 340B drugs purchased. CMS wanted this new lower reimbursement rate for such PBDs to be the same lower rate established in the CY 2018 OPPS Final Rule[5] applicable to hospitals paid under OPPS and enrolled in the 340B Program, such as disproportionate share hospitals and their grandfathered PBD sites, *i.e.*, excepted off-campus PBDs.

CMS's stated rationale for establishing 340B payment parity between different types of PBDs – excepted and nonexcepted – was to reduce beneficiary cost-sharing for drugs and move toward site neutrality, *i.e.*, establishing the same payment amount for the same items and services furnished in the hospital outpatient setting and physician office setting. (Read Katten's recently published Client Advisory on site neutrality developments here.) CMS stated:

> [T]he difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments – excepted off-campus PBDs versus nonexcepted off-campus PBDs – creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act.[6]

The 340B reimbursement reduction policies announced by CMS for CYs 2018 and 2019 were invalidated in a litigation brought by the American Hospital

[4] 83 Fed. Reg. 58818, 59015-22 (Nov. 21, 2018).

[5] 82 Fed. Reg. 52356 (Nov. 13, 2017).

[6] CY 2019 OPPS Proposed Rule, 83 Fed. Reg. 37046, 37145 (July 31, 2018).

UPCOMING EVENTS

Michael R. Callahan

Defending Against Patient Safety Act Discovery Requests – Case Law Development and Lessons Learned

Children's Hospital Association
Child Health PSO Webinar
Dec. 5

Michael R. Callahan

Patient Safety Work Product Privilege in the Context of Patient Safety Organizations

University of California Professional
Medical Hospital Liability Program
Oakland, CA | Dec. 20

Joseph V. Willey and Alessandra Denis

Topic: Medicaid Program Integrity

Katten Webinar
January 2020 (exact date TBD)

Cheryl Camin Murray, J. David Washburn and Kenya Scott Woodruff

Healthcare: an Economic Engine in M&A

North Texas Economic Forum
Dallas, TX | Jan. 21

Association, in which the US District Court for the District of Columbia held that the imposition of those rate reductions exceeded the US Department of Health and Human Services (HHS) Secretary's authority.[7] However, the District Court did not rescind the reductions given the complexities in doing so, deciding instead to remand the relief issue to HHS to devise an appropriate remedy.[8] The CY 2020 OPPS Final Rule acknowledges this pending litigation and the Court's mandate to have HHS fashion relief. Thus, CMS, in the CY 2020 Proposed Rule,[9] solicited comments regarding how to "formulate a solution that accounts for all of the complexities that the district court recognized." (84 Fed. Reg. 39504)

Any specific remedy that CMS develops for CYs 2018 and 2019 on the basis of comments received may be included in the proposed CY 2021 OPPS Proposed Rule, as well as any necessary changes to the CY 2020 rates required by a court order. However, CMS stated that it intends to pursue its appeal rights, and the 340B reductions are included in the CY 2020 OPPS Final Rule in the event it does win on appeal. In the meantime, recognizing that it may not win on appeal, CMS is taking steps to develop a court-ordered remedy.

CMS has suggested that the remedy it devises may take into account the results of a 340B hospital survey CMS intends to conduct of drug acquisition cost data for CY 2018 and 2019.[10] CMS anticipates that this survey will confirm that its current Average Sales Price minus 22.5 percent rate is a conservative measure that, according to CMS, overcompensates 340B hospitals. CMS stated that "a remedy that relies on such survey data could avoid the remedial complexities" discussed in the CY2020 Proposed and Final Rules, since "the district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available."[11]

Whether CMS will ultimately be successful in its efforts to reduce 340B reimbursement remains uncertain due to the pending litigation. Katten's Health Care team continues to monitor this litigation, along with other 340B policy revisions and developments.

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[7] Decisions in *American Hospital Association et al. v. Azar et al.*, No. 1:18–cv–02084 (D.D.C. Dec. 27, 2018 and May 6, 2019).

[8] May 6, 2019 Decision, *supra* note 7; discussed at 84 Fed. Reg. 39504.

[9] 84 Fed. Reg. 39398 (Aug. 9, 2019).

[10] 84 Fed. Reg. 51590 (Sept. 30, 2019).

[11] CY 2020 OPPS Final Rule, 84 Fed. Reg. 61142, 61322 (Nov. 12, 2019).

Integrating Medical Staffs: Challenges, Options and Proposed Solutions

AUTHOR

Michael R. Callahan

Introduction

Barely a day goes by without reading in a newspaper, health care journal or publication about a proposed hospital merger, acquisition or affiliation in which smaller hospitals are being absorbed into a larger health system, or even much larger mergers as evidenced by the recent affiliation between Dignity Health and Catholic Health Initiatives to form CommonSpirit. There are many factors driving this movement towards consolidation, but one important challenge, which is sometimes lost among the complexities of these transactions, is the effort to integrate the medical staffs within these organizations. I expect that every hospital administrator, medical staff leader, in-house legal counsel, Chief Medical Officer, medical services professional and others reading this article has been or will be on the front lines in dealing with the associated political, practical and legal implications of efforts to achieve successful integration.

The purpose of this article is to identify a number of the key challenges hospitals will confront, as well as options and proposed solutions to consider when addressing these issues.

Industry environment overview

There are a number of factors that affect a standalone, or even a small hospital system, when considering whether to become part of a larger regional or national health care network. Because of ever decreasing reimbursement by both federal and state governments under the Medicare and Medicaid programs, as well as efforts to reduce costs by private payors, hospitals are required to reduce their own costs and to find ways to increase efficiencies. This has led to reductions in staff and non-profitable services and other necessary steps in order to have a positive bottom line. In addition, as hospital facilities begin to age there is the expectation from a market and patient standpoint to continuously upgrade and modernize their facilities and equipment in order to better compete with other area hospitals. This means that the access to capital in the financial markets becomes even more important but difficult to achieve if the hospital is not successfully making its yearly budget. In fact, many hospitals continue to lose millions of dollars every single year forcing them to rely on fundraising efforts and their investment returns.

A standalone hospital or small system also is confronted with the loss or reduction in its ability to compete and to exercise any type of leverage with insurance companies when engaged in managed care contract negotiations. Larger systems have greater coverage and greater leverage in these types of negotiations, which can sometimes result in smaller hospitals being left out of various managed care networks. Based on these and other market factors, a standalone hospital is faced with the prospect of trying to continue to go it alone or, instead, to begin negotiations with surrounding competitors and health care systems as a means of continued survival.

Challenges, options and proposed solutions

A single unified medical staff

One of the goals and certainly a consideration for any health care system, whether as a whole or by region depending on the size of the system, is to consider the establishment of a single unified medical staff. Some of the advantages of a single unified medical staff include the following:

- uniform appointment, reappointment and hearing process across the system for all physicians and advanced practitioners;
- uniform policies and procedures;
- the single unified medical staff can be for the entire system or for different hospitals within a defined region or division;
- the amendment process for bylaws, rules, regulations and policies is more streamlined; and
- uniform eligibility criteria for clinical privileges, as well as the adoption of uniform OPPE and FPPE standards, that will make it easier to improve the delivery of quality health care services and to track outcomes for meeting various pay for performance and other value-based standards.

Although the benefits of establishing a single unified medical staff would suggest that all systems would move in this direction, the challenges to achieve these results are considerable and include the following:

- abiding by the Medicare Conditions of Participation (CoPs), which sets forth a detailed list of requirements that include the creation of a single board of directors for all of the hospitals, and the amendment of current bylaws requiring that each medical staff approve the development of a single unified medical staff along, with the option of reverting back to an independent medical staff at some point in time in the future;
- managing disparate medical staff cultures, medical staff profiles, such as employed versus independent members, different geography and different payor mix;

- choosing the best model set of bylaws and policies between the different hospitals: In a multi-state system, one must take into account the different state regulatory requirements and whether the state will even approve of a single unified medical staff or a sole corporate member for all of the licensed hospitals;
- navigating the different standards in different states as to which professionals can actually serve on the medical staff; and
- combating the perception of medical staffs that moving to a single unified system will have the effect of undermining their existing autonomy and independent voices.

In light of these somewhat formidable obstacles, health care systems have considered and adopted other methods designed to achieve at least some of the benefits of a single unified medical staff. These include the following:

- adoption of common bylaw provisions, such as the pre-application process, appointment, reappointment and hearing procedures, but maintaining the individual medical staff and leadership structure at each hospital;
- creation of a CVO;
- creation of a centralized credentials committee for the system or by region;
- adoption of the same or similar bylaws but with different cover sheets for each hospital; and
- adoption of a uniform Board policy to prevent competing physicians from obtaining and maintaining membership and clinical privileges.

The use of these different methods are sometimes more than sufficient to create the degree of "systemness" which the organization is attempting to achieve. Once these methods are in place, it may also make it easier to move towards a single unified medical staff, if that still makes sense for the organization.

Significantly different medical staff bylaws, rules and regulations

Although the existence of varying and even wildly different medical staff bylaws, rules and regulations may seem like a major impediment to achieving some of the benefits of "systemness", there are other reasons why these differences make sense and might even be preferred. Some of these include:

- the differences reflect disparate cultures, geography and historical nuances — helps to keep the peace;
- for multi-state systems, bylaws could reflect different state standards for compliance, peer review, licensure and medical staff eligibility standards;
- the different hospitals might be under different accreditation standards even though all must comply with the Medicare CoPs; and
- bylaws and regulations are likely to be less uniform if the system is composed of academic medical centers, suburban, rural and critical access hospitals — one size does not fit all.

Despite some of the reasons and rationale for the different medical staff organizational documents, these difference do indeed create a number of obstacles in light of the current industry efforts to move from volume to value as a basis of reimbursement. These include:

- differences can serve as an impediment to future consolidation, collaboration and efficiencies;
- conflicts in FPPE, OPPE, peer review and related standards and eligibility criteria and requirements undermine efforts to upgrade and maintain the quality of the medical staff;
- compliance issues for some hospitals in meeting the Medicare CoPs, accreditation and statutory requirements;
- efforts to adopt uniform provisions can be difficult at best and time consuming;

- issues, for example, with how the medical staff bylaws define the term "investigation" for purposes of Data Bank reporting versus what is considered routine peer review; and
- different standards for what does and does not trigger a hearing.

In attempting to address some of these problems and the resulting inefficiencies towards improving patient care services, some methods to consider in limiting the adverse impact of these differences include the following:

- conduct a compliance audit in order to determine whether there are regulatory, legal and other compliance gaps, and then fix them;
- if seeking to adopt some uniform provisions, do a comparison check to see how similar or different are the existing bylaws and regulations;
- determine if the hospital or the medical staff controls the process for prescreening;
- seek common ground through the use of a medical staff committee with representatives from each of the facilities;
- try to sync-up the appointment and reappointment procedures and reappointment schedules; and
- create a system/region/bylaw committee with appropriate medical staff representation.

Keep in mind that, although uniformity with some of these standards across the system in many ways makes sense, making these changes on a regional or division basis may be more easily achievable depending on the commonality of these existing policies procedures and bylaws. Overlapping medical staffs will be more likely to appreciate common approaches to obtaining and maintaining memberships and clinical privileges.

Conflicting credentialing/privileging/eligibility criteria

If there is one area which, in my opinion, poses the most significant legal liability risk from a negligent credentialing standpoint, it is where the hospitals have different credentialing, privileging and eligibility criteria as it relates to the granting of clinical privileges. That said, there are some reasons why such differences exist and which may even make sense, at least for the initial period of time after a single hospital joins a larger system. These include:

- allowing for diverse members and categories in order to avoid loss of medical staff members who may be motivated to leave the hospital and join competing systems;
- maintaining differences avoids the need to terminate clinical privileges or provide hearing rights if the physician would no longer be eligible for certain privileges and, therefore, would lose these privileges; and
- acknowledging that under accreditation standards, privileges do need to be site specific and also will depend on the nature of clinical services offered by the hospital.

But the problems and risks of not attempting to change these diverse standards are significant on many different levels, such as:

- alleged breaches of standard of care depending on the degree of differences as reflected in department criteria and policies such as the use or non use of core privileges and different eligibility standards;
- privileges inadvertently granted to competitors at one facility who would be prohibited from obtaining and maintaining membership at an affiliated hospital depending on prescreening and other eligibility standards;
- utilization/quality standards relied upon for demonstrating current competency at some, but not all, facilities could create different standards of care, potentially resulting in increased liability;
- lack of uniform adoption of required quality metric/outcome standards imposed by ACOs, private payors and others will have a direct adverse impact on a hospital's reimbursement;

- different FPPE/OPPE standards could result in physicians being allowed to maintain privileges at one facility while losing them at another facility as well as give rise to different standards of care; and
- different and conflicting code of conduct/disruptive behavior/HIPAA/ conflict of interest policies also can create confusion particularly with hospitals that have overlapping medical staff members.

Some solutions or options to consider in moving towards more uniform standards include:

- conduct a comprehensive analysis to determine the degree of differences in criteria and potential for resulting in greater legal liability and adverse impact on reimbursement;
- examine the impact on a physician's existing privileges – who wins and who loses and are hearing rights triggered;
- establish if there a legitimate basis to grandfather some of these physicians, as is typically done regarding the issue of board certification;
- allow for a 12 to 24 month period in which to meet any uniform criteria which are adopted. If not met, then privileges are voluntarily relinquished with no Data Bank reporting obligations;
- closely monitor during the interim period for outcomes for those physicians which are allowed to maintain clinical privileges at lower standards;
- utilize a multidisciplinary committee to evaluate and identify common standards; and
- amend bylaws and policies accordingly.

Conflicting privilege and immunity statutes and provisions

Of critical importance to every hospital and health care system is taking appropriate steps to maximize their privilege, confidentiality and immunity protections under state and federal law. That said, looking at medical staff bylaws within an existing system frequently reveals that they have not done so. This is particularly problematic for hospitals that are within the same state. Obviously, in a multi-state system the privilege, confidentiality and immunity provisions in each state could be different, therefore requiring that there be different bylaws and policies adopted to access these protections.

For those systems that have not taken advantage of joining a Patient Safety Organization (PSO) under the Patient Safety and Quality Improvement Act of 2005, particularly for a multi-state system, the disadvantages are considerable:

- tracking changes in state peer review statutes and the applicable case law for multi state systems is not easily accomplished and could lead to different bylaws, policies and practices, regarding what information is privileged and what actions are eligible for immunity protection;
- waiver issues also vary, especially if sharing confidential information across state lines and even within a system, depending on the categories of providers who can access the protections;
- in the context of CINs/ACOs the scope of activities and provider facilities that are covered under the various protections may be different; and
- conflicting peer review policies and procedures and, therefore, different scope of privilege protections can create confusion with overlapping medical staffs.

There are some options and considerations to be explored by a hospital or health system in order to achieve maximum privilege, confidentiality and immunity protections, including:

- HCQIA immunity protections have been adopted by most states thereby giving the system a base level of immunity protections;

- both state and HCQIA immunity provisions could apply depending on the facts and circumstances of the litigation dispute in question; and
- participating in a PSO under the Patient Safety and Quality Improvement Act of 2005 offers clarity regarding:
  - scope of privileged patient safety activities under the Patient Safety Act are typically broader than activities under state privilege protections;
  - the Patient Safety Act privilege applies to all licensed facilities in the state;
  - privileged information can be freely shared among affiliated providers throughout the system;
  - privilege protections apply in all state and federal proceedings, whereas state peer review statutes will only apply in state court and state court causes of action (i.e., defamation and breach of contract, but not in federal court for federal actions such as in discrimination or antitrust claims);
  - the Patient Safety Act allows a non-provider corporate parent to be considered a provider and therefore part of a single system patient safety evaluation system, enabling it to access the privilege protections; and
  - the privilege under the Patient Safety Act can never be waived under any circumstances.

Economic credentialing issues

In the past, and even now, the term "economic credentialing" triggers various legal and emotional issues depending on whether you are the hospital or an independent medical staff member. Generally speaking, the decision of whether to grant or not grant membership and clinical privilege based on economic factors is not illegal. In some states, such as Illinois, it is legally permissible if handled in the correct manner. The question of whether hospitals can make appointment and reappointment decisions based on economic factors has become even more relevant recently in light of the growth of hospital systems and the increased competition that exists between such systems and hospitals. For example, one would expect that, if a hospital grants membership to a primary care physician or other specialist who is employed by a competing system or has a competing facility, the provider will use every reasonable opportunity to transfer or ultimately admit patients to its own hospital or facility. Because such transfers result in loss of business and revenue and, in addition, have an adverse impact on a system's ability to maintain a continuity of high quality health care services, hospitals have become more selective over which physicians may obtain and maintain membership and clinical privileges.

For these reasons, a number of systems are developing pre-screening applications which focus on questions of whether an interested physician is employed by a competing group, has a financial interest in a competing facility or otherwise has significant conflicts of interest. Under such policies these physicians do not even get an application. Because the decision is not based on quality of care concerns or the competency of the physician, the decision not to grant privileges is not reportable to the Data Bank.

In order to be more legally enforceable, such policies which have the effect of excluding the applicants or even which have the effect of terminating existing members of the medical staff, which is somewhat controversial, need to be adopted by the board of directors rather than medical staff driven. Under such policies, the board looks to issues such as continuity of care, quality, costs and utilization, as well as identified adverse economic impacts affecting the system, when granting privileges to competing medical staff physicians.

Although there are reasonable economic and legal reasons to support such an initiative, moving towards such a policy is not without its political and other difficulties, which include:

- legal challenges based on allegations of illegal competition, discrimination, breach of contract, tortious interference, etc., especially if applied to existing members without some form of hearing;
- difficulty in obtaining medical staff adoption despite the quality of care, economic and related reasons to support such a policy;

- well-documented justification is required;
- if the medical staff controls the pre-application forum and process, it may be difficult to include economic screening questions; and
- amending bylaws to authorize adoption of these standards is probably more difficult but has been achieved by other systems.

For some systems that have moved in this direction, the hospital has been able to demonstrate the adverse economic impact of allowing competing physicians to continue to obtain and maintain clinical privileges at the hospital. Such adverse consequences may include the inability to update equipment, hire additional support staff (including physicians and advanced practitioners), provide updated facilities to meet physician needs, and to be better prepared to compete for managed care contracting.

Working with appropriate medical staff representation when presenting the justification for such policies, hospitals should work in a collaborative effort to:

- evaluate pre-screening, pre-application forms and applications to see what questions are being asked and then to modify in order to screen out competitors;
- develop standard forms and conflict of interest policies across the system;
- establish a conflict of interest policy designed to determine whether the physician not only has economic interest or a relationship with competing facilities, but also whether s/he serves in leadership positions and/or has contractual relationships with competing facilities; and
- strive to incorporate the board policy and standards in these appointment and reappointment restrictions into the medical staff bylaws, although such an effort may be politically difficult at best.

Impact on existing exclusive contracts

Most, if not all, hospitals have entered into exclusive provider agreements, particularly in the areas of radiology, pathology, anesthesiology and, sometimes, emergency room services. Others have even extended these arrangements into more specialized surgical services such as obstetrics and cardiac surgery.

Because such exclusive contracts often have many benefits that justified these contracts in the first place, there are obvious reasons for maintaining these relationships, which include:

- continuing existing exclusive contracts that have been in effect for some period of time can help to achieve continuity of quality health care services given the familiarity which the group has with the hospital and supporting personnel, the use of equipment and other benefits derived from these relationships;
- maintaining the existing groups' help to continue the referral relationships between the hospital and its existing medical staff members; and
- existing groups may already be staffing more than one system hospital, so changing groups could be significantly disruptive.

Despite these benefits, problems have been identified within a system when deciding whether to maintain these contractual relationships, including:

- different exclusive groups that have conflicting contracts terms (e.g., is there a clean sweep provision whereby hearing rights are waived if an individual is terminated from the group or the group is terminated by the hospital?);
- quality results and standards of care could vary;

- whether all the groups required to participate in managed care and other contractual arrangements;
- differences between the groups that are employed versus those under contract and the impact on apparent agency liability claims must be examined; and
- will some hospitals have a problem recruiting replacement physicians given their location or payor mix or need to provide the group a monetary subsidy.

To address this issue of lack of uniformity, some alternatives to consider include:

- merging the groups by a specific region rather than engaging a group to cover the entire system. (As a practical matter, most groups might not be able to cover the entire system anyway);
- issuing a request for proposal between existing and/or outside groups; and
- working, at a minimum, towards standardized agreements/requirements/standards of care as well as reporting outcomes within the group to the hospital, in addition to sharing outcome information by and between the groups.

There are a variety of challenges that all hospitals will face when participating in hospital mergers and attempting to integrate disparate medical staffs based on geography, culture, academic medical center versus small community hospital, employed versus independent medical staffs and other significant differences. The better prepared the hospital and it's medical staff and other supporting cast members are at identifying these challenges, the better prepared all will be in adding value to the combined efforts of all in achieving successful medical staff integration.

10 Post-Deal Steps for Health Care Entities

AUTHOR

Lisa M. Prather

Your health care company has just completed the acquisition of, or merger or joint venture with, another company. The process likely took several months, and involved more time, money and effort by more people than you anticipated, but the deal "closed" and you and your team spent the past 24 hours feeling relieved and celebratory.

So, now what? You know there are a few matters to address after completion of the deal, but there is the regular day-to-day running of your business to continue, not to mention, catching up on things which were de-prioritized the past few months while everyone focused on the deal. If, however, you do not address all of the post-closing matters for the deal, your company may end up with significant issues to address in the future — whether its five months or five years from now. To help ensure the deal you are currently celebrating does not turn into the deal that derails the company's future, you should consider taking specific actions to complete the transition and fully understand the details of everything your company inherited as part of the deal.

1. ***Person in charge of post-deal matters.*** Designate one (or possibly two) person(s) to serve as the primary point of contact for all post-deal matters. Optimally, you would have had someone start transition and integration steps prior to closing the deal who would then continue the efforts post-close. This should be someone familiar with the deal and the desired outcomes of the deal, and someone with authority to facilitate cooperation from other departments. The post-deal matters will likely consume more than half of this person's workload for at least a few months, so ensure the person has bandwidth to devote the post-deal matters. If you do not have a person like this within your company, consider using an outside attorney who assisted you with the deal.
2. ***Required notices and filings with third parties.*** Hopefully, diligence for the deal identified all required notices related to the deal, especially since some may have needed to be completed prior to closing the deal. Notifying federal and state agencies of changes of ownership or other material changes affecting

licenses and permits, as well as ensuring all contractually required notices, must be a primary focus for your organization. If not required pre-close, the notice period usually ranges from ten to thirty days post-close. And, if your organization is the entity sold or acquired, then you want to promptly provide notices in order to limit your liability going forward.

3. ***Optional notices and filings with third parties.*** Certain notices may not be "required," but it is a best practice to provide courtesy updates to contracted parties or state licensing agencies, especially if the key contact person, address, phone or email for the organization has changed. Since you will be preparing documents for the required notices, it should not require much additional time or effort to provide the optional notices.
4. ***Update corporate filings and corporate governance documents.*** It is important to update your company's filings with applicable secretary of state offices. Did your deal result in: A change to members or directors of your company? A different principal place of business or registered agent? The specific states in which you conduct business? The assumed names you want to use? Ensure that your internal documents (bylaws, operating agreements) and required state filings are updated and consistent with one another.
5. ***Review acquired contracts for compliance.*** The pre-deal diligence process (hopefully) identified and excluded from the deal any highly problematic contracts. For all contracts remaining in place post-deal, you should review these agreements in detail to ensure compliance with laws and compliance with your company's policies. Simply because a space lease appears compliant as written, have its terms been complied with — has rent been paid timely and, if not, any late fees collected? Have annual rent increases been calculated and collected appropriately? Do employment agreements mention benefits which the acquiring company does not offer?
6. ***Amend or terminate acquired contracts as necessary.*** Once you identify any contracts which do not comply with law or your policies, the next step is to effectively amend or terminate those contracts, which may prove challenging and time intensive. Renegotiating a professional services agreement, especially if the revisions affect a physician's compensation, may be a challenging discussion. Updating an equipment lease in place for several years, because the value of the equipment has depreciated and newer technology is available for a similar price, requires time and effort to obtain valuations and renegotiate terms of the lease.
7. ***Combine acquired contracts with existing contracts.*** If you already use a contracts database (or other tracking system), or if you acquired one as part of the deal, you need to ensure all contracts (existing and acquired) are incorporated into the same system and have similar tracking measures applied to them. Usually, this requires manually entering information from the contract into the database (i.e., party names, effective date, renewal or expiration date, etc.) and setting reminders to ensure the contract does not lapse or automatically renew under terms you had anticipated updating upon renewal.
8. ***Consolidate vendor functions and agreements.*** As a general rule, you likely want only one EHR system, linen supply company, or printer/copier supplier, etc. Effectively transitioning to one vendor for these items and terminating the contract with the vendor no longer needed may take time, expertise (especially for technology matters), and negotiations to avoid impacts, such as fees, related to early termination of contracts.
9. ***Identifying issues subject to indemnification/insurance under the terms of the deal.*** Most deals establish a set amount of time, typically somewhere from six months to two years, during which the purchaser may identify issues with what has been acquired and be financially compensated under rep and warranty insurance, indemnification, and/or special escrow account provisions for the deal. The above-mentioned contracts review and remediation process can aid in identifying some of these matters, but you may need specialists from various areas of your organization (e.g., accounting, managed care, IT) tasked with critically assessing or auditing various functions and agreements.

10. ***Disclosure of issues discovered to government entities.*** In working through the above steps, you may uncover a matter that requires disclosure or reporting to a government authority. Whether it is a fraud and abuse matter, a tax or accounting matter, a patient information security matter, or some other issue, the more timely you identify the issue, end the period of non-compliance and report the matter to the government, the better chance you have of limiting your liability or at least reducing any fines and penalties.

It is difficult to consider all of the post-deal matters to address prior to closing a deal, much less in the early stages of considering and structuring a deal. Factoring in the post-deal time, resources and costs from the outset of a deal, however, should improve the long-term outcomes of the deal and could prove to be financially beneficial as well.

Recap of Proposed Changes to the Stark Law and the Anti-Kickback Statute

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On October 17, the Centers for Medicare & Medicaid Services and the Office of Inspector General published for public comment proposed rules to 1) establish new Stark Law exceptions and clarify regulations; and 2) add Anti-Kickback Statute safe harbor protections for certain coordinated care and associated value-based arrangements. Comments on the proposed rules are due by December 31, 2019. For more information, see the following Katten advisories:

- "CMS Proposes Sweeping Revision to the Stark Law," October 17, 2019
- "OIG Proposes to Add and Expand AKS Safe Harbors," October 21, 2019