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News for North Carolina Hospitals
from the Health Law Attorneys of Poyner Spruill LLP



Proposed 2017 Hospital OPPS Rule Would End Medicare Payments to Many Off-Campus Facilities at the Same Levels as Hospital-Based Outpatient Departments

by Wilson Hayman

Published on July 14, 2016, CMS's proposed 2017 Hospital Outpatient Prospective Payment System (OPPS) rule calls for site-neutral payments that would stop Medicare payments made to many off-campus facilities that are at the same level as payments to hospital-based departments.

In its commentary to the proposed rule, CMS notes the dramatic trend in recent years toward hospital acquisition of physician practices and the integration of those practices into hospital departments, which has resulted in higher Medicare payments and beneficiary cost-sharing. The higher payments are due to Medicare's payment of two separate claims for services provided in an off-campus department of a hospital — one under the OPPS for institutional services, and the other under the Medicare Physician Fee Schedule (MPFS) for professional services. In its news release, CMS indicated that these higher payments made to hospital-owned facilities for essentially the same services provided for a lower cost in freestanding facilities have been a long-standing concern of the HHS's Office of Inspector General, the Medicare Payment Advisory Commission, and members of Congress.

In Section 603 of the Bipartisan Budget Act of 2015 (the Budget Act), Congress amended the OPPS statute to provide that as of January 1, 2017, "applicable items and services" furnished by certain off-campus outpatient departments of a hospital will not be considered a covered hospital outpatient provider-based department (PBD) service for purposes of payment under the OPPS. Such items and services will instead be paid "under the applicable payment systems" under Medicare Part B. CMS has estimated

that these changes would reduce OPPS spending by approximately \$500 million in 2017 alone, and the Congressional Budget Office estimates \$9.3 billion over a ten-year period.

EXCEPTED ITEMS AND SERVICES

The Budget Act exempted from these new requirements any such off-campus outpatient departments existing prior to the Budget Act's enactment on November 2, 2015, but only for the same types of items and services they had furnished and billed under the OPPS prior to that date. In light of the perceived congressional intent to curb hospitals' acquisition of physician practices, CMS has proposed in the new rule to apply this exception only to existing off-campus departments as of that date, and not to a department that has been relocated either to another location or another suite or unit in the same building.

Specifically, CMS proposes to exempt from this new rule off-campus outpatient department items and services provided at one of these three locations, which would continue to be paid under OPPS: (1) a dedicated emergency department that meets one of several requirements; (2) on-campus locations, using the current definition of "campus"; and (3) departments at or within 250 yards of a "remote location" that have been recognized as having provider-based status (collectively referred to as "excepted items and services"). Further, CMS proposes to limit the exception for off-campus programs billed under OPPS to those items and services which are part of one or more of 19 "clinical family of services" of hospital outpatient service types named in the rule (see 81 Fed. Reg. at 45685), if those types of services had been furnished on-site and billed prior to November

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Proposed 2017 Hospital OPSS Rule

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2, 2015. Presumably, services beyond one of the 19 clinical family of services may not be billed under OPSS even if they were furnished and billed as of that date, and a hospital could not expand the services provided at excepted off-campus outpatient PBDs and bill for the new services under OPSS.

CMS proposes that an off-campus hospital outpatient PBD may be transferred and continue to bill under OPSS only if the ownership of the main hospital or provider is also transferred and the Medicare provider agreement is accepted by the new owner. If the provider agreement is terminated, off-campus PBDs that bill under OPSS would no longer be excepted. Individual, excepted off-campus PBDs may not be transferred from one hospital to another (without transferring the main hospital) and retain their excepted status.

ALTERNATIVE PAYMENT SYSTEM

CMS does not currently have a mechanism to pay the off-campus PBD for non-excepted items and services other than the OPSS. It has indicated that numerous complex system changes, including creating a new provider or supplier type for the non-excepted off-campus PBDs, may be needed to allow an off-campus PBD to bill and be paid under a different payment system. Such operational changes may include new enrollment forms, claims forms, and hospital cost reports, among others. Consequently, CMS proposes that as a one-year, interim solution beginning January 1, 2017, non-excepted items and services at off-campus PBDs will be paid under the MPFS at the nonfacility rate, and no separate facility payment will be made. CMS has solicited public comments concerning a new payment system other than OPSS to be used by off-campus PBDs beginning January 1, 2018, to bill for non-excepted items and services.

HOSPITALS' RESPONSES AND OUTSTANDING QUESTIONS

In the proposed rule, CMS has taken a restrictive interpretation to the provisions of Section 603, which did not address such issues as how a change in ownership or relocation of grandfathered facilities would affect items and services by excepted off-campus PBDs paid under the OPSS. CMS's proposals met with sharp responses from hospital groups, who have criticized the limitations imposed on new off-campus hospital PBDs and on relocating or building new outpatient facilities. Critics believe these steps will seriously undermine hospitals' ability to provide care to underserved communities.

Many questions remain, including reimbursement and requirements under the future alternative payment system as of January 1, 2018. In soliciting public comments due on September 6, 2016, CMS raised additional issues not covered by the proposed rule. These topics, which may be addressed by the final rule or in future rulemaking, are as follows:

- Whether it should adopt a limited relocation exception process for natural disasters and other specific, extraordinary circumstances beyond the hospital's control;
- Whether it should require hospitals to separately self-report the items and services furnished by each off-campus outpatient PBD, the date they began billing for those services, and the clinical families of services provided there prior to that date;
- The 19 proposed "clinical families of services" that may continue to be billed under OPSS, if other requirements are met;
- Whether CMS should adopt a specific time period within which the prior items and services had to have been billed in order to be exempted;
- Whether CMS should also limit the volume of services furnished within a clinical family of services for which the hospital was billing prior to November 2, 2015;
- The impact of other billing rules, fraud and abuse laws, and other statutes, rules and provisions on these proposals; and
- The changes needed to enrollment forms, claim forms and hospital cost reports, among other operational changes.

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Changes to Compensation Rules for Tax-Exempt Hospitals

by Kelsey Mayo

The IRS has proposed new rules that will require tax-exempt hospitals (and other tax-exempt entities) to review a variety of compensation arrangements to avoid unintended tax consequences. This article will provide a brief overview of the potential impact of these new rules and steps that tax-exempt hospitals can take now to avoid problems later.

WHAT COMPENSATION ARRANGEMENTS ARE AFFECTED?

Special rules (often referred to as “457 rules”) apply to “deferred” compensation of tax-exempt entities, including nonprofit and governmental hospitals. Deferred compensation can come in a wide variety of forms, including paid time off, death and disability benefits, severance benefits, bonuses, and retirement benefits. Deferred compensation from a tax-exempt entity will be taxed to the employee as soon as it is vested (even if the employee won’t receive the money in that year!) unless the amount is deferred under certain retirement plans or under a “bona fide” severance, disability, death benefit, or sick leave and vacation leave plan.

CHANGES TO THE RULES

Recent changes proposed by the IRS modify many of these special 457 rules, including changing when an amount is considered deferred (and thereby subject to the accelerated taxation), when an amount is considered vested (which may be earlier than you would imagine), and what types of arrangements are considered bona fide severance, disability, death benefit, and sick leave and vacation leave plans.

Here are just a few examples of how the modified rules may affect a tax-exempt hospital’s compensation arrangements:

- If the timing of bonus payments and documentation of the bonus plan do not meet the new rules, all or part of the bonuses may be taxable to employees in a year before they are actually paid to the employees.

- If the hospital’s severance arrangement allows severance to be paid on both involuntary and voluntary terminations or if it does not meet certain limits on timing and amount, the value of the severance may be taxable to the employee before the year in which it is actually paid to the employee.
- If the hospital’s paid-time-off plan is very generous and allows the employee to roll over PTO from year to year, the PTO may be taxable to the employee when earned (rather than when the PTO is actually paid out to the employee).

NEXT STEPS FOR COMPLIANCE

To ensure compliance with the new rules (and avoid unintentional tax consequences for employees), tax-exempt hospitals should:

- Review employment agreements with bonuses, severance, disability payments, or special vacation arrangements.
- If severance is offered:
 - Make sure a severance plan/policy is in place that meets the applicable payment timing requirements
 - Reconsider or redesign any severance plan that allows payment on voluntary terminations
- Review and possibly tweak (or more clearly document) bonus plans to ensure they clearly meet the rules.
- Review any supplemental retirement plan or incentive plan, and, if necessary, redesign the plan to meet the new requirements.
- Review vacation and paid-time-off arrangements for compliance with the new rules.

The new rules will be effective after final regulations are published. We expect the rules to be effective beginning January 1, 2018, and they will apply to new arrangements and to current arrangements that continue after the effective date.

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Nondiscrimination Final Rule Under the ACA Imposes New Requirements for Hospitals

by Iain Stauffer

On May 26, 2016, the United States Department of Health and Human Services (HHS), Office of Civil Rights (OCR) issued the “Nondiscrimination in Health Programs and Activities” final rule, implementing Section 1557 of the Affordable Care Act (ACA). Generally, Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities. The final rule provides guidance to covered entities regarding their legal obligations under Section 1557 and educates consumers about their rights. With certain exceptions, this rule became effective July 18, 2016. Has your hospital taken the necessary steps to ensure compliance?

WHO IS COVERED BY THIS RULE?

This rule applies to all entities operating health programs or activities that receive federal financial assistance from HHS, health programs or activities administered by HHS, the health insurance marketplaces and the plans offered by issuers that participate in the marketplaces. The rule refers to these as “covered entities.” While federal financial assistance includes Medicaid and Medicare Parts A, C, and D, it does not include payments made under Medicare Part B. In addition to hospitals, covered entities can include health clinics, physicians’ practices, community health centers, nursing homes, rehabilitation centers, health insurance issuers, and state Medicaid agencies.

WHAT DOES THE FINAL RULE COVER?

Section 1557 builds on existing and long-standing federal civil rights laws and nondiscrimination regulations. This final rule “clarifies and codifies” existing nondiscrimination requirements and provides new protections prohibiting discrimination on the basis of sex in health programs and activities. Generally, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any covered entity.

The final rule sets out requirements in the following areas: meaningful access for individuals with limited English proficiency (LEP); effective communication for individuals with disabilities; accessibility standards for buildings and facilities; accessibility of electronic and information technology; reasonable accommodations; equal program access on the basis of sex; nondiscrimination in health-related insurance and coverage; employer liability for discrimination in employee health benefit programs; and nondiscrimination on the basis of association.

RESPONSIBLE EMPLOYEE AND GRIEVANCE PROCEDURE

If a covered entity has 15 or more employees, the entity must designate a responsible employee to coordinate the entity’s efforts to comply with and carry out the responsibilities of Section 1557 and this final rule, which include investigating grievances.

Covered entities with 15 or more employees must also adopt a grievance procedure that incorporates due process standards and provides for a prompt and equitable resolution of grievances. Appendix C of the final rule provides a model grievance procedure covered entities may use. Also, if a covered entity has an existing grievance procedure, the entity may combine it with the grievance procedure required by this rule.

NOTICE REQUIREMENTS

The final rule imposes new notice requirements for all covered entities to notify beneficiaries, enrollees, applicants, and the public. Covered entities must comply with the final rule notice requirements by October 16, 2016. The required notice must contain the following:

- That the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;

- That the covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternative formats, free of charge and in a timely manner, when such aids and services are necessary to ensure individuals with disabilities have an equal opportunity to participate;
- That the covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with LEP;
- How to obtain the aids and services;
- The identification of and contact information for the designated responsible employee, if applicable;
- The availability of the covered entity's grievance policy and how to file a grievance, if applicable; and
- How to file a discrimination complaint with the HHS OCR.

This notice must be posted in a conspicuous font size in conspicuous physical locations where the covered entity interacts with the public; in a conspicuous location on the covered entity's website, accessible from the home page of the covered entity's website; and in significant publications and communications targeted to beneficiaries, enrollees, applicants, and members of the public. The publications and communications contemplated by the rule would likely include outreach, education, marketing materials, patient handbooks, notices requiring a response, and notices pertaining to rights and benefits. Along with the notice, the covered entity must post taglines in at least the top 15 languages spoken by individuals with LEP in North Carolina. A tagline is a short statement written in a non-English language that indicates the availability of language assistance services free of charge. The HHS website (<http://www.hhs.gov>) contains a sample and translated versions of a notice of nondiscrimination, statement of nondiscrimination, and taglines for covered entities.

Significant publications and communications that are small-size postcards and tri-fold brochures, for example, need only contain an abbreviated nondiscrimination statement and taglines in at least the top two languages spoken by individuals with LEP in North Carolina. Appendix A of the final rule contains samples of the notice and nondiscrimination statement covered entities may use.

ENFORCEMENT

The final rule also includes potential enforcement mechanisms. It authorizes lawsuits by aggrieved individuals to challenge alleged violations of Section 1557 and also provides for compensatory damages. In addition, the OCR can enforce Section 1557 through informal means, denying, suspending, or terminating federal financial assistance, or it may refer the matter to the United States Department of Justice.

WHAT SHOULD A PROVIDER DO?

If covered entities have not already done so, they need to review their policies and procedures to ensure they comply with the nondiscrimination provisions of the final rule. In addition, covered entities with 15 or more employees need to verify they have designated a responsible employee and adopted a grievance procedure. All covered entities need to prepare their notices and taglines to ensure compliance with the posting requirements by the October 16, 2016 deadline. Covered entities should consult with counsel for a detailed review of the nondiscrimination rule to resolve questions and to discuss its specific requirements and applicability so that they may comply with Section 1557 and this final rule.

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Your Money or Your Data: Ten Things You Need To Know About Ransomware

by Saad Gul and Mike Slipsky

In 2013, hackers attacked a venerable Swansea, Massachusetts institution via ransomware. Ransomware is software that locks users out of computers or specific files until the victim pays a “fee” to release the lock. Such attacks have become increasingly common in recent years, with hospitals and health systems being frequent targets. Typically, any institution reliant on real-time or near-real-time access to data can be subject to ransomware attacks. The twist in the Swansea incident was the victim: the Swansea Police Department.

In addition to targeting the occasional law enforcement agency, ransomware has had other interesting implications. When Medstar was infected, it reportedly developed a partial workaround by reverting to pen and paper files. This could be seen as the latest manifestation of cyber-defense measures which have ranged from the Kremlin’s rumored decision to revert to typewriters to the U.S. Navy’s decision to reinstate training in celestial navigation as a backup to computer calculations. While a series of high-profile ransomware attacks in 2016 have raised public awareness, the full legal and practical implications of the phenomenon are still being worked out. Here is what we know:

1. Ransomware has a pedigree. The earliest known incident occurred at a 1989 World Health Conference. A conference attendee distributed 20,000 infected floppy disks to participants. Victims were instructed to mail payment to a postal box in Panama. The perpetrator was quickly apprehended, but variants of the scheme continue to evolve. In recent years, the advent and ubiquitous presence of the Internet has made it exponentially easier to distribute ransomware infections.
2. The United States government’s position on ransomware payments is conflicted. Law enforcement frowns on payoffs, which inevitably breed the next generation of attacks. However, FBI officials have acknowledged that “we often advise people just to pay the ransom.” Queried by Senator

Ron Wyden, the FBI clarified that it advised payment only if no mitigation steps were available and as the sole alternative to permanent loss of the data. The government has had some success – it has stopped some platforms and botnets and seized others, but the magnitude and continuous evolution of the problem defies a ready solution.

3. The government itself is a target. In addition to the Swansea police, a number of other institutions have been attacked and have paid ransoms, including the Lincoln County, Maine, Sheriff’s Office and the Midlothian, Illinois Police Department. Law enforcement’s willingness to pay is a tacit acknowledgment of both the intractability of the problem and the legal appropriateness of making otherwise unseemly payments.
4. Victims’ willingness to pay ransoms is a function of the fact that most ransomware perpetrators keep their demands relatively low – around \$300 is the average. Moreover, while there is no guarantee that payment of the ransom will release the locked system, there appears to be an “honor among thieves” ethos whereby most attackers live up to their end of the bargain. Many go so far as to send “customer service surveys” to targets, seeking “feedback” on their “service.”
5. Distinguishing ransomware from more reputable business practices is not always a clear-cut exercise. Communications from self-designated “security firms” may identify specific security gaps in a company’s IT system and then seek payment for consulting services. Such a communication may or may not be a ransomware attack. The distinction hinges on many factors, including (1) whether data was accessed in violation of the federal Computer Fraud and Abuse Act, (2) whether failure to retain the security firm would result in the loss of data and (3) whether the communicator has barred the owner from accessing any part of its own system.

6. On the other end of the spectrum, the ransomware demand is often cast as a legal notice from the FBI or other law enforcement agency. The recipient is warned that the computer has been electronically seized for illegal activity, often terrorism or pornography. Many recipients elect to pay a “fine” to release their equipment; the embarrassment and fear accompanying the taint of illegal activity makes such victims more willing to pay.
7. Ransomware is becoming increasingly ominous with the advent of the Internet of Things. The FDA has recently advised medical manufacturers to evaluate and address cyber gaps in their products; even otherwise innocuous gaps provide a potential incursion route that leaves the entire product or connected system vulnerable to ransomware hijacking.
8. The Department of Health and Human Services has recently issued guidance on ransomware. The current HHS view is that a ransomware attack is a “security incident” under HIPAA but may not amount to a full breach if certain onerous conditions are met. However, since the applicable HIPAA regulations define a breach as including unauthorized “access” to data, covered entities should treat each incident as a breach until proven otherwise.
9. The term “cyber insurance” covers a wide range of potential risks. However, payments for cyber extortion or ransomware are an increasingly popular component. While most ransomware payments fall below the typical self-insured retention, such insurance is an option worth considering. Insurance comes with considerable caveats, including the duty to cooperate with the insurer, obtaining consent, and nondisclosure. However, insurers frequently offer expert assistance which can make the coverage attractive even if it is never triggered.
10. Finally, like virtually all cyber scourges, while ransomware cannot be eradicated, a few simple preventive measures can pay disproportionate dividends. While ransomware can infiltrate systems remotely, the vast majority of incidents can be traced to human error – the clicking of links, the opening of emails, or the utilization of accessories such as jump drives that serve as Trojan horses for ransomware. Regular and consistent backups – preferably secured with an “air firewall” (i.e. disconnected from networked systems) – also go a long way in alleviating the threat. A recent FTC panel suggested that even a full backup was not required; merely backing up the most “system critical” components would go a long way toward defusing the threat. Exercises and contingency planning also serve to identify weaknesses and develop triage plans ahead of an actual emergency. In cyber planning, as in war, the company that sweats ahead of time can hope not to bleed come the crunch time.

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Changes to Compensation Rules

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Every tax-exempt hospital should review its employment agreements and any deferred compensation arrangements as soon as possible; modifying these arrangements can take a significant amount of time due to the required approval process. We also recommend budgeting for the review and modification of other affected arrangements (such as paid-time-off policies, severance policies, bonus plans, and deferred compensation arrangements) in the next year. We can help with this process by providing customized estimates – please don't hesitate to ask.

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