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Healthcare Reform

Final Rule Update: New Enrollment and Payment Suspension Rules Affect All Medicare, Medicaid, and CHIP Providers and Suppliers

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, made significant changes to Medicare, Medicaid, and the Children's Health Insurance Program to reduce fraud, waste, and abuse at the provider enrollment level of program participation. On September 23, 2010, the Centers for Medicare & Medicaid Services issued a proposed rule that implemented the ACA's provisions addressing fraud, waste, and abuse at the enrollment level. The Proposed Rule included new requirements regarding enrollment screening, an enrolling application fee, payment suspension, temporary moratoria on enrollment, compliance programs, and provider and supplier termination. This article summarizes the changes in the final rule with comment period, which was published in the *Federal Register* on February 2, 2011. Continue reading on page 10.

Final Rule Update: CMS Extends Deadlines, Issues Clarifications on Redistribution of Unused Residency Slots Under PPACA

On August 3, 2010, the Centers for Medicare & Medicaid Services published a proposed rule providing proposed guidelines for the redistribution of unused residency slots under Section 5503 of the Patient Protection and Affordable Care Act. On November 24, 2010, CMS published a Final Rule that largely adopted the provisions of the Proposed Rule discussed in our earlier article. However, CMS made several changes in the Final Rule that should be noted. Continue reading on page 17.

Editor's Note:

Continuing our monitoring of healthcare reform implementation, this edition of *The RAP Sheet* again features two articles focusing on some aspect of the implementation of the Patient Protection and Affordable Care Act. Two articles summarize final rules issued to implement pieces of the reform legislation. We expect to include at least one article on healthcare reform in future editions of *The RAP Sheet*.

Initial Enrollments and Changes of Ownership Impacted by Home Health Medicare Enrollment Rule Changes

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In the 2011 Home Health Prospective Payment System Rate Update Rule, the Centers for Medicare & Medicaid Services (CMS) modified home health agency (HHA) Medicare provider enrollment provisions in two important ways. First, it extended the amount of time that a Medicare-certified HHA must meet initial capitalization requirements. Second, it narrowed the scope of business transactions that are subject to the so-called 36-Month Rule, which causes the deactivation of an HHA's Medicare billing entitlements upon the occurrence of certain HHA ownership transfers that occur within three years of the last ownership change.

Overview of the New Rule

HHA Capitalization

Since 1998, HHAs have been required to prove that they have adequate start-up working capital upon initial Medicare enrollment, or when participating in selected change of ownership (CHOW) transactions that result in "a new provider number being issued."[1] The pre-2011 requirement was set forth in an HHA-specific Medicare certification rule that provided that an HHA must prove that it has three months of available working capital at the time of Medicare provider enrollment. Under the new rule, an HHA must satisfy the working capital requirement at the time of enrollment, during the entire initial enrollment process, and for the first three months after enrollment.[2]

CMS' stated rationale for modifying the rule was to address situations in which the HHA has sufficient working capital at the time the HHA submitted its Medicare enrollment application, but did not have these same funds on hand at the time that the Medicare enrollment application was eventually approved some months later.[3] CMS acknowledged the reality that an HHA may have to operate for many months before it has the benefit of a Medicare revenue stream even under the best of circumstances. The purpose of the amendments is to make sure that the HHA can financially survive until its Medicare accounts receivable are being collected and the funds are available to pay the HHA's obligations, such as meeting payroll.

The provider enrollment rules now provide additional tools for Medicare contractors to verify capitalization more than once during the enrollment process, by permitting:

1. The contractor to deny billing privileges to an applicant who does not provide proof that they have the required "initial reserve operating funds" within thirty days of a Medicare or contractor request;[4]
2. The revocation of Medicare billing privileges of any HHA that fails to comply with a CMS or Medicare contractor request to prove that it meets the capitalization requirements at any time during the provider enrollment process and the three months thereafter;[5] and
3. The denial of Medicare billing privileges to an HHA unless the HHA meets the initial working capital requirements.[6]

It is clear in commentary to the new rules that CMS expects (but the rule does not require) Medicare contractors to verify that the working capital funds that were present at the time of submission of the enrollment application are still available to the HHA later on in the enrollment process.

By building in additional enrollment processes, it is likely that the change may extend the amount of time it takes an HHA to successfully enroll in the Medicare program. If the rule, as implemented, causes Medicare contractors processing HHA enrollment applications to verify capitalization more than once, it is likely that enrollment delays will increase an HHA's need for working capital during the HHA's start-up phase because of the longer enrollment period. Before, the HHA could simply include the financial information with its Medicare application, submitted before the HHA commenced operations; now it appears that the HHA should expect the Medicare contractor to request verification again at some later point in the enrollment process and to process this additional information after it is submitted.

The 36-Month Rule

It does appear that the ability to engage in legitimate business transactions got slightly easier for HHAs as a result of changes to the 36-Month Rule. CMS has developed reasonable exceptions to the previous rule, which essentially banned the purchase and sale of Medicare-participating HHAs more frequently than once every three years.

Background—Transactional Structures—Initial Enrollment, CHOW, and Changes of Information[7]

In order to understand and analyze the changes to the 36-Month Rule, it is helpful to understand the way various business transactions are treated for Medicare enrollment purposes, and the different impacts each has on the Medicare provider agreement and the collection of the provider's Medicare accounts receivable.

Initial Enrollment

The "initial enrollment" process is the way new providers get into the Medicare program. In an initial Medicare enrollment, a provider may only submit a Medicare application thirty days prior to the date that the provider is to commence providing services.[8] The Medicare contractor generally takes a minimum of several months (and sometimes many months) to review and approve even a well-packaged application. The provider must then secure a survey by CMS or an accrediting body with deeming authority to complete the enrollment process. Medicare billing privileges commence the date that a successful survey is passed.[9] HHAs that are subject to the 36-Month Rule would be required to use the initial enrollment process.

CHOW

Some sales of Medicare providers constitute Changes of Ownership (CHOWs); others do not. With respect to a corporation, Medicare regulations provide that:

> [t]he merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes a change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.[10]

The importance of whether or not a CHOW has occurred significantly affects the Medicare and Medicaid billing processes for the buyer and seller in the transaction. The operating company's Medicare billing entitlements do not terminate upon the sale of a business that does not constitute a CHOW, such as a sale of all of the outstanding shares of a corporation. Providers that experience a CHOW transaction, however, are able to use the selling provider's Medicare billing entitlements for a period of time after the closing of the business transaction but before the CHOW process has been finally approved by CMS, which occurs sometime after the transaction closes.[11]

Providers experiencing a CHOW that choose not to accept the assignment of the selling provider's Medicare provider agreement will be required to use the "initial enrollment process," which invariably necessitates a gap in the HHA's Medicare billing entitlements and thus an important source of revenue for a period of time until the initial application process has concluded and a survey arranged. For these reasons, business transactions are frequently structured with reference to the Medicare CHOW rules and their impact on the flow of funds into the HHA.

For providers who choose to use the CHOW process, the assignment of the seller's provider agreement to a purchaser occurs on the transfer of the business and the purchaser's billing privileges can commence on that date. Depending on the billing arrangement between seller and buyer, it is possible that there can be only minimal interruptions in the billing privileges of the HHA that experiences a CHOW.[12] There will be no uncompensated Medicare care based on a failure of the HHA to be properly enrolled.

Providers that experience a CHOW but choose not to accept assignment of the seller's provider agreement have all billing entitlements cease on the date that the CHOW occurs.[13] In this situation, an HHA that purchases a business would either discharge Medicare beneficiaries on or before the date of the purchase if this can be done without running afoul of patient abandonment rules or provide uncompensated care to Medicare beneficiaries for an unknown period of time until the date of the Medicare certification survey.

Changes of Information

The "changes of information" process is the required means of reporting changes to a provider's Medicare file that are not CHOWs to CMS.[14] With some exceptions, these changes must be reported within ninety days of the occurrence[15] and simply serve as an update to the Medicare file. As a general rule, they do not routinely impact the flow of Medicare receivables except to the extent that they assist the provider in continuing to meet eligibility for Medicare payment. Transfers of stock in a company (whether 5% of the operating company's stock or 100%) would generally be reported to the Medicare program through this mechanism.

The "Old" 36-Month Rule

The old 36-Month Rule, effective only for 2010, provided that:

> If an owner of a home health agency sells (including asset sales or stock transfers), transfers or relinquishes ownership of the HHA within thirty-six months after the effective date of the HHA's enrollment in Medicare, the provider agreement and Medicare billing privileges do not convey to the new owner.[16]

Under these circumstances, the HHA must engage in an initial Medicare enrollment process, including a new survey.[17] While the heading that preceded the old 36-Month Rule was called "change of ownership," it was clear by its application to stock sales that the 36-Month Rule applied not only to Medicare CHOWs, but also to non-CHOW transactions that previously were subjected to a mere change of information file update that did not affect the HHA's ongoing stream of Medicare receivables.

According to CMS, the 36-Month Rule is in place to prevent the sustenance of HHA "flipping" (e.g., rapidly selling the HHA) or the HHA "certificate mill" process by which organizations, working with brokers, enroll in the Medicare program with the sole purpose of transferring the established Medicare revenue stream and provider agreement to a purchaser after the enrollment occurs.[18] Nonetheless, the effect of the rule on legitimate providers engaging in above-board business transactions cannot be overstated.

The consequence of application of the 36-Month Rule is that the HHA's Medicare billing entitlements are deactivated on the date of the sale transaction and the initial enrollment process is the means by which the HHA can get back into the Medicare program. Medicare applications for initial enrollment cannot be

submitted until thirty days prior to the date that the business will become operational to the new owner. Medicare application processing times can be as few as sixty days after the date that the application is received by the Medicare contractor, but can frequently take many months. The effective date of the provider agreement of an HHA whose Medicare billing entitlements have been deactivated is unpredictable, and is in large part beyond the HHA's control. Instead, this date is within the control of the Medicare contractor reviewing the application and partially dependent upon CMS or accreditation surveyors and the date they are willing to schedule the HHA survey. This process is unpredictable and gives legitimate buyers of an HHA little comfort in the purchase of a business as an ongoing concern. Buyers seeking to sell an HHA within three years of purchase are faced with the unattractive choices of providing Medicare services for some months on an uncompensated basis or arranging for the transfer of patients to providers, if any in the area, and thereby foregoing some of the traditional benefits available in the purchase of a business with an established patient and referral basis. Purchasers dependent upon capital from lenders face particular challenges in using HHAs as sources of collateral given the restrictions on sales and the limitations on lenders needing to foreclose on an outstanding loan.

The old rule initially left open questions such as the threshold for triggering the 36-Month Rule—would a minor sale of stock (e.g., 5%) trigger the application of the rule and thus deactivate a provider's Medicare billing privileges if it occurred within three years of any other similar transfer? CMS ultimately released several interpretations to the old 36-Month Rule that would have applied the severe rule to situations in which a mere 5% stock or asset sale, or a change request reporting a change in partners, regardless of the percentage of ownership.[19] Backlash against implementation was significant, and these interpretations were rescinded by CMS.

The "New" 36-Month Rule

The new rule has injected several reasonable exceptions to the 36-Month Rule to permit legitimate transactions by established Medicare providers to proceed. First, the modified rule narrows the circumstances in which it applies. The new 36-Month Rule introduces the concept of an HHA "change in majority ownership" (CMO) and specifies that the rule applies only in the event of a CMO. A "CMO" occurs when an "individual or organization acquires more than a 50% direct ownership interest in an HHA during the thirty-six months following the HHA's initial enrollment into the Medicare program or the thirty-six months following the HHA's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation."[20] A CMO includes cumulative changes that occur within a thirty-six-month period.[21]

While the CMO is broader than the traditional Medicare CHOW, it is narrower than the old 36-Month Rule in that it applies only to significant (50% or more) transactions, and distinguishes between "direct" and "indirect" ownership transfers. This implies that a CMO applies to stock transactions at the level of the Medicare operating company's shareholders, rather than more remote transfers (e.g., owners of shareholders of a Medicare HHA).

There are several exceptions to the new rule. Under the new rule, the following HHAs are exempt from the 36-Month Rule:

- HHAs that have submitted two consecutive years of full-cost reports;
- HHAs whose parent company experiences an internal corporate restructuring, such as a merger or consolidation;
- An HHA operating company that experiences a legal conversion from one entity type to another (such as conversion of an entity from a corporation to a limited liability company, for example) so that the indirect owners of the operating company did not change; or
- When an individual owner of an HHA dies.[22]

With these new exceptions, it appears HHA transactions got a little easier. Given the great consequences of application of the 36-Month Rule, the HHA community is expected to welcome efforts to narrow its scope.

Conclusion

Consistent with CMS' goals in enacting the new enrollment rules, HHAs seeking enrollment in the Medicare program need to be prepared to stay in business for the long haul. Recent changes to Medicare provider enrollment rules will require that HHAs have larger amounts of capital than ever before. HHAs will continue to be impacted in business transactions by the application of the 36-Month Rule except in very narrow circumstances.

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1 42 C.F.R. § 489.28 (as in effect in 2010).
2 *Id.* § 424.510(d)(9).
3 *Id.* § 489.28.
4 *Id.* § 424.510(d)(9).
5 *Id.* § 424.535(a)(11).
6 *Id.* § 489.28(g).
7 This discussion is limited to the process used by Medicare providers for whom a CHOW process is available, such as HHAs, and does not apply to certain Part B providers such as medical groups.
8 CMS Program Integrity Manual Chapter 15 § 15.8.1.
9 42 C.F.R. § 489.13(b).
10 *Id.* § 489.18.
11 CMS Program Integrity Manual Chapter, § 5.5.2.5.
12 *Id.*
13 *See* CMS State Operations manual Chapter 3 § 3210.5.
14 *See* form CMS 855A, page 6 and 855B, page 5.
15 42 C.F.R. § 424.516(e).
16 *See id.* § 424.550(b)(1) effective January 1, 2010.
17 *Id.*
18 75 Fed. Reg. 70419-70420.
19 CMS Program Integrity Manual Transmittal 318, which has been rescinded; *see also* MLN Matters Number MM6750, also rescinded.
20 *See* new 42 C.F.R. § 424.502.
21 *Id.*
22 *Id.* § 424.550(b)(2)(iv) effective January 1, 2009.

Catching Up to Technology: Proton Beam Therapy Coverage and Reimbursement Principles Continue to Evolve

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Editor's Note:

The November 2009 edition of *The RAP Sheet* featured an article previewing reimbursement issues arising from a fast-emerging technology known as "proton beam therapy" in an article entitled "Ensuring Appropriate Incentives for Proton Beam Therapy: A Review of the Medicare Reimbursement Landscape." The following article summarizes recent developments for Medicare coverage and reimbursement for this fast-growing service.

Proton beam radiation therapy has significantly developed over the last few years with treatment centers coming online in Illinois, Virginia, Oklahoma, and Pennsylvania. In addition, intentions to build new centers have been announced in locations throughout the country, including Arizona, California, Maryland, Minnesota, New York, Ohio, and Tennessee.[1] This article is a summary of recent developments in the Medicare payment and coverage for proton beam radiation therapy (Proton Therapy).

Payment Update

Proton Therapy centers generally are enrolled in Medicare as either (1) hospital provider-based centers or (2) freestanding centers. With respect to hospital provider-based centers, the payment rates are set nationally through the Medicare Hospital Outpatient Prospective Payment System (HOPPS) based on cost data reported by hospitals—*See* Figure 1 on page 6.

With respect to Proton Therapy provided in freestanding centers, the various Medicare Administrative Contractors (MACs) establish the payment rates. Given the relatively small number of freestanding centers currently operating in the United States, only a small number of MACs have set payment rates for Proton Therapy (First Coast Options Services (First Coast), National Government Services (NGS), and Trailblazer Health Enterprises (Trailblazer))—*See* Figure 2 on page 6.

Coverage Update

To date, the Centers for Medicare & Medicaid Services (CMS) has not adopted a National Coverage Determination for Proton Therapy. However, a number of Medicare contractors have adopted or proposed Local Coverage Determinations (LCDs). Most recently (December 2010), Wisconsin Physicians Service Insurance Corporation (WPS) issued a proposed LCD—WPS is conducting a series of meetings and comments are due on the proposed LCD by March 27, 2011—*See* Figure 3 on page 7.

What Is on the Horizon

Looking beyond the above snapshot of Proton Therapy payment and coverage, the Proton Therapy reimbursement landscape is likely to continue to evolve in the coming years as new centers come online and additional MACs address this newer technology for their Medicare beneficiaries. In addition, research efforts are underway to study Proton Therapy, including comparative effectiveness research designed to compare Proton Therapy to numerous other treatment modalities. This research is highly likely to be relied upon by payors in establishing Proton Therapy reimbursement. For example, the recently proposed WPS LCD cited two Agency for Health Care Research & Quality reports: "Particle Beam Radiation Therapies for Cancer, Revised November 2009" and "Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer, February 2008." In addition, the National Institutes of Health convened a conference in December to discuss comparative effectiveness research and a number of presenters, including payor representatives, addressed Proton Therapy and the need for additional research.

Given this evolving landscape, Proton Therapy stakeholders will want to (1) actively engage in Proton Therapy research efforts, and (2) continue to monitor and engage in the Medicare reimbursement dialogue from the policy, payment, and coverage perspectives to monitor this promising technology as a cancer treatment option for Medicare beneficiaries.

1 The following is a sample of articles and media releases related to recently announced Proton Therapy centers:
- http://minnesota.publicradio.org/display/web/2010/11/16/proton-beam-cancer-mayo/
- www.sdbj.com/news/2011/jan/10/200m-proton-therapy-centers-deliver-cancer-fightin/
- http://articles.baltimoresun.com/2010-10-14/health/bs-hs-proton-cancer-20101013_1_proton-therapy-cancer-treatment-radiation-therapy
- www.dotmed.com/news/story/14231/
- www.medcitynews.com/2010/09/does-dayton-really-need-two-proton-therapy-centers/
- www.knoxnews.com/news/2010/may/27/proton-therapy-center-okd-for-development/.

2 First Coast has indicated that it will be re-evaluating the Proton Therapy codes and may be implementing new pricing later in 2011.

Figure 1—Summary of HOPPS Payment Rates for Proton Therapy in Hospital Provider-Based Centers, 2006-2011.

National Medicare Proton Therapy Rates for Hospital Outpatient Departments						
	2006	2007	2008	2009	2010	2011
APC 664	$947.93	$1161.29	$816.59	$703.38	$942.31	$1,031.71
APC 667	$1134.08	$1389.37	$977.09	$840.56	$1232.67	$1,349.61

Figure 2—MAC Payment Rates for Proton Therapy in Freestanding Centers, 2008-2011.

MAC Proton Therapy Rates for Freestanding Proton Therapy Centers					
MAC	Year	CPT®			
		77520	77522	77523	77525
Trailblazer (Houston)	2008	$905.34	$936.96	$973.52	$1086.64
	2009	$845.56	$875.08	$909.22	$1014.84
	2010* (1/1 - 5/31)	$852.67	$882.43	$916.86	$1023.37
	2010* (6/1 - 12/31)	$881.43	$901.85	$937.03	$1045.89
	2011	$800.42	$828.40	$860.76	$960.86
Trailblazer (Oklahoma)	2008	$769.21	$796.18	$827.37	$923.86
	2009	$726.44	$751.88	$781.31	$872.36
	2010* (1/1 - 5/31)	$790.37	$818.08	$850.12	$949.21
	2010* (6/1 - 12/31)	$807.94	$836.25	$868.99	$970.29
	2011	$746.27	$772.41	$802.65	$896.19
Trailblazer (Virginia) (Targeted to transition to Palmetto GBA in mid March 2011)	2010	$849.15	$878.90	$913.31	$1019.75
	2011	$787.26	$814.84	$846.74	$945.43
First Coast (Florida)	2008	$905.25	$936.93	$973.14	$1086.30
	2009	$915.21	$947.24	$983.84	$1098.25
	2010	$915.21	$947.24	$983.84	$1098.25
	2011[2]	$935.34	$968.08	$1,005.48	$1,122.41
NGS (Indiana)	2008	$518.94	$518.94	$786.34	$786.34
	2009	$524.65	$524.65	$794.99	$794.99
	2010	$524.65	$524.65	$794.99	$794.99
	2011	$536.19	$536.19	$812.48	$812.48
Palmetto GBA (Virginia) (Targeted to transition from Trailblazer in mid March 2011)	2011	As of 1/11/2011, Palmetto GBA had not established payment rates for proton beam therapy.			
Wisconsin Physicians Service Insurance Corporation (WPS) (Illinois)	2010	As of 1/6/2011, WPS had not established payment rates for proton beam therapy.			
	2011				

Figure 3— Summary of Local Coverage Determinations for Proton Therapy

(Note: The Medicare program has been and continues to consolidate the Medicare program contractors, e.g., from fiscal intermediaries and carriers to Medicare Parts A & B MACs. Due to a number of factors, including contractor appeals, the Medicare contractors for a number of jurisdictions are still in flux. In the chart below, the authors have identified those jurisdictions that are currently in flux. However, the authors note that the contractor consolidation is an evolving dynamic.)

Contractor	Jurisdiction	Summary of LCD
First Coast (Medicare Parts A & B MAC)	Florida, Puerto Rico, and Virgin Islands	• Provides a short list of conditions for which Proton Therapy will be considered medically reasonable and necessary. • Provides a second list of conditions that "may be" considered medically reasonable and necessary. However, for the second list of conditions, a rigorous medical necessity standard must be met and the patient must be treated as part of a clinical trial. • All other indications are not considered reasonable and necessary. • Includes a number of documentation requirements. • First Coast also issued a draft LCD for "Radiation Therapy for Basal Cell and Squamous Cell Carcinomas" in October 2010 that indicates that proton beam therapy is not covered for Stage T1 basal cell carcinoma or squamous cell carcinoma. (The comment period for this draft LCD ended on 11/29/2010).
Trailblazer **(Medicare Parts A & B MAC)**	Colorado, New Mexico, Oklahoma, Texas, and Virginia (until 3/19/2011)	• "Because proton beam therapy is relatively new and available in only a few locations, the provider/physician will need to contact Medicare to discuss indications and payment. Each claim will be individually reviewed." • Trailblazer also issued a draft Proton Beam Radiotherapy LCD for Virginia, where it is a Carrier, on February 23, 2006 (Draft Trailblazer LCD). In summary, the Draft Trailblazer LCD was a least-costly alternative type policy and included a list of conditions for which Proton Therapy was medically necessary. In addition, the Draft Trailblazer LCD included a list of conditions for which Proton Therapy would be priced the same as IMRT. Under the Draft Trailblazer LCD, Proton Therapy for all other conditions would be priced the same as conventional radiotherapy. The Draft Trailblazer LCD has not been finalized, and Trailblazer has indicated that reimbursement policy would be handled on a case-by-case basis.
NGS **(Medicare Parts A & B MAC & legacy carrier / fiscal intermediary) (Part of NGS' jurisdiction is under CMS contractor rebidding "corrective action" and may be subject to rebid and assignment to a different contractor.)**	Indiana (Carrier), Connecticut (A/B MAC), Kentucky (Carrier), and New York (A/B MAC) (Note: NGS appears to have jurisdiction in several states where the provider has selected National Government Services as the provider's Medicare Part A fiscal intermediary and has not been transitioned to a Medicare Parts A & B MAC)	• In a recently retired LCD, the following language appeared: "Because proton treatment delivery is relatively new and available in only a few locations, the carrier in which one of these is located will need to contact that provider *to discuss indications* and payment."

Figure 3 *continued*

Noridian Administrative Services LLC **(Medicare Parts A & B MAC)**	Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming	• The medical record must clearly evidence the medical necessity of proton radiotherapy in lieu of other modalities of treatment.
Palmetto GBA **(Medicare Parts A & B MAC)**	American Samoa, California (Northern and Southern), Nevada, Guam, Hawaii, North Carolina, Northern Mariana Islands, South Carolina, Virginia (Targeted to start in mid March 2011), and West Virginia	• The medical record must clearly evidence the medical necessity of proton radiotherapy in lieu of other modalities of treatment.
Highmark Medicare Services **(Medicare Parts A & B MAC)**	Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania	• Highmark issued a Proton Therapy LCD, effective October 28, 2009, that, in brief: – Provides a list of conditions for which Proton Therapy is considered medically reasonable and necessary. – Provides that Proton Therapy is indicated when: (1) The dose volume histogram illustrates at least three critical structures or organs protected by the use of Proton Therapy; (2) the dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissues; (3) there is documented clinical rationale that doses are generally thought to be above the level otherwise attainable with other radiation methods might improve control rates; or (4) there is documented clinical rational that higher levels of precision associated with Proton Therapy compared to other radiation treatments are clinically necessary. – With respect to prostate cancer, requires: (1) physician documentation of patient selection criteria (stage and other factors); (2) documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits; and (3) documentation of the specific reasons why Proton Therapy was the treatment of choice for the specific patient. Other factors considered favorable for coverage include enrollment of the patient in an appropriate clinical registry for planned assessment and publication. • Includes a number of specific documentation requirements.
WPS **(Medicare Parts A & B MAC & legacy carrier / fiscal intermediary) (Part of WPS' jurisdiction is under CMS contractor rebidding "corrective action" and may be subject to rebid and assignment to a different contractor.)**	Nebraska (A/B MAC), Minnesota (Carrier), Missouri (A/B MAC), Kansas (A/B MAC), Illinois (Carrier) Iowa (A/B MAC), and Wisconsin (Carrier) (Note: Wisconsin Physicians Service Insurance Corporation appears to have jurisdiction in all states where the provider has selected Wisconsin Physicians Service Insurance Corporation	• WPS has a historical LCD that states, "Clinical use of proton beam therapy is relatively new and there are no facilities available within our jurisdiction at the present time." • On December 1, 2010, WPS issued a proposed LCD for Proton Therapy. • The proposed LCD provides a short list of conditions for which Proton Therapy will be considered medically reasonable and necessary. • The WPS proposed LCD then provides a second list of conditions that "may be" considered medically reasonable

Figure 3 *continued*

	as the provider's Medicare Part A fiscal intermediary and has not been transitioned to a Medicare Parts A &B MAC)	and necessary. However, for the second list of conditions, a rigorous medical necessity standard must be met and the patient must be treated as part of a clinical trial. • With respect to prostate cancer, the draft LCD includes prostate cancer on the second list of conditions for which Proton Therapy "may" be considered medically reasonable and necessary. Further, the draft LCD provides as follows: "There is as yet no good comparative data to determine whether or not Proton Beam Therapy for prostate cancer is superior, inferior, or equivalent to external beam radiation, IMRT, or brachytherapy in terms of safety or efficacy. The prostate cancer should be locally advanced prostate cancer (i.e., Stages C or D1 [without distant metastases], also classified as T3 or T4) (the tumor has spread through the capsule on one or both sides but has not invaded seminal vesicles or other structures) and any N disease (either no spread to lymph nodes or there has been spread to the regional lymph nodes Note: Spread beyond local lymph nodes is considered metastatic disease. Coverage and payments of Proton Beam Therapy for prostate cancer will require: (a) Physician documentation of patient selection criteria (stage and other factors); (b) Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits; and (c) Documentation of the specific reasons why Proton Beam was the treatment of choice for the specific patient. Other factors considered favorable for coverage include enrollment of the patient in an appropriate clinical registry for planned assessment and publication." • Lastly, the proposed LCD provides that, "If a patient cannot clearly meet the criteria for coverage but desires proton beam radiotherapy based on a marketed theoretical advantage, the claim should be billed with the appropriate modifier appended to the treatment delivery code." • The proposed LCD also includes a number of documentation requirements. • WPS planned a number of advisory committee meetings between 1/28/2011 and 2/10/2011. • Comments on the proposed LCD are due by March 27, 2011.
National Heritage Insurance Company Corp. **(Medicare Parts A & B MAC)**	Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	• National Heritage Insurance Company Corp. has not issued a LCD that addresses Proton Therapy.

Healthcare Reform

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Editor's Note:

The January 2011 edition of *The RAP Sheet* featured an analysis of the *proposed* rule on new enrollment and payment suspension requirements mandated by healthcare reform. The following is an update based on the February 2, 2011, final rule. We greatly appreciate the authors of the prior analysis providing this update as well.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010[1] (Affordable Care Act or ACA), made significant changes to Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) to reduce fraud, waste, and abuse at the provider enrollment level of program participation. On September 23, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule (Proposed Rule) that implemented the ACA's provisions addressing fraud, waste, and abuse at the enrollment level. The Proposed Rule included new requirements regarding enrollment screening, an enrolling application fee, payment suspension, temporary moratoria on enrollment, compliance programs, and provider and supplier termination. This article summarizes the changes in the final rule with comment period, which was published in the *Federal Register* on February 2, 2011 (Final Rule).[2]

Screening Under Medicare, Medicaid, and CHIP

In the Final Rule, CMS maintained the three categories of providers classified according to the risk of fraud, waste, and abuse—limited, moderate, and high. Those risk levels in turn affect the level of screening procedures the enrollee will undergo.[3] As finalized, effective as of *March 23, 2011*, the new risk categories and the related enrollment screening procedures will be applicable to newly enrolling providers and suppliers as well as to those currently enrolled providers and suppliers whose revalidation is scheduled between March 25, 2011, and March 23, 2012.[4] For providers and suppliers assigned to the high screening level, the fingerprint-based criminal history record check requirement will be implemented through sub-regulatory guidance and will be effective sixty days following the publication of that guidance. All other screening requirements are effective on March 25, 2011, for those in the high screening level. For all other currently enrolled providers and suppliers, ACA established and the Final Rule confirmed an effective date of March 23, 2012.

Screening Categories—Medicare

In the Final Rule, CMS added certain provider and supplier types to the categories and eliminated others. We have included a revised chart (and affiliated endnotes) showing some of the changes below—noting additions with underlined text and deletions with a ~~strikethrough~~—*See* Figure 1 on page 11.

As noted in the Final Rule, commenters urged CMS to more narrowly tailor its risk assignments by geography because previously, fraud, waste, and abuse issues with DMEPOS suppliers and home health agencies (HHAs) have been shown in certain geographical regions (e.g., South Florida, Texas, and California), and it is not clear that issues with such entities are national.[5] CMS disagreed that the enhanced screening procedures should initially be restricted to high-risk geographical areas, noting, "While some regions of the country evidence fraud, waste and abuse more than others, fraudulent activity can occur anywhere."[6] Further, CMS stated that the national approach is the most objective in implementing the screening procedures. To address concerns in particular regions, CMS stated that it will rely on other program integrity tools, including, without limitation, the enrollment moratoria authority contained in the Final Rule.[7]

CMS also declined to subcategorize individual providers and suppliers based on their ownership. As such, there is no default "limited" risk category based on being publicly traded; publicly traded and private companies are treated the same. HHAs owned by hospitals are considered "moderate" or "high" risk based on the HHA provider placement, not based on the hospital ownership. The DMEPOS suppliers also are classified in the moderate- or high-risk category despite ownership by physicians, a community pharmacy, a physical therapist, or an occupational therapist. Ambulance services suppliers now are solely categorized in the "moderate" risk category, rather than as limited or moderate, based on whether the supplier has public or government ownership or affiliation.

Figure 1—Proposed Assignments of Provider Types to Risk Categories (Medicare)

Limited	Moderate	High
• Physicians, non-physician practitioners (NPPs) (including nurse practitioners, certified registered nurse anesthetists (CRNAs), occupational therapists, speech language pathologists, and audiologists), medical groups, and clinics • Pharmacies newly enrolling or revalidating via the CMS-855B • Hospitals, including critical access hospitals • Skilled nursing facilities • Federally qualified health centers (FQHCs) • Medical clinics • Group practices • ~~Publicly traded providers or suppliers~~ • Ambulatory surgical centers • End stage renal disease facilities • Portable x-ray suppliers • Others[8]	• Comprehensive outpatient rehabilitation facilities • Independent diagnostic testing facilities (IDTFs) • Independent clinical laboratories • Currently enrolled (re-validating) HHAs • Currently enrolled (re-validating) suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) • Hospice organizations • Physical therapists and PT groups • Portable x-ray suppliers • Others[9]	• Newly enrolled HHAs • Newly enrolled suppliers of DMEPOS

Although several commenters thought accreditation should lower the risk category, CMS stated that they do not believe that accrediting bodies perform a sufficient level of oversight to ensure that the entities they accredit are a low program integrity risk.[10] According to CMS, accrediting bodies assist in verifying the supplier's or provider's compliance with Medicare standards, rather than assess the provider's or supplier's risk of fraud, waste, or abuse.

Moving to "High" Risk—Medicare

In the Final Rule, CMS revised the reasons to move providers and suppliers from a limited- or moderate-risk level to the high-risk level. CMS eliminated the identity theft reason, where CMS has evidence from or concerning a physician or NPP that another individual is using his/her identity, as a basis for moving a provider or supplier into a high-risk screening level.[11] CMS maintained the following reasons from the Proposed Rule for moving a provider or supplier to a high-risk level:

- The provider or supplier has been excluded by the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) or had its Medicare billing privileges revoked by a Medicare contractor within the previous ten years and is attempting to establish additional Medicare billing privileges for a new practice location or by enrolling as a new provider or supplier.
- CMS imposes a payment suspension.
- The provider has been terminated or otherwise precluded from billing Medicaid.
- CMS lifts a temporary moratorium applicable to such providers or suppliers at which point the move to the high-risk level will last for six months after the lifting of the moratorium.[12]

CMS added "final adverse action" as a basis for reassigning a provider or supplier to the high screening level.[13] "Final adverse action" is defined at 42 C.F.R. § 424.502 as one of the following actions:

(1) A Medicare-imposed revocation of any Medicare billing privileges;

(2) Suspension or revocation of a license to provide healthcare by any state licensing authority;

(3) Revocation or suspension by an accreditation organization;

(4) A conviction of a federal or state felony offense (as defined in § 424.535(a)(3)(i)) within the last ten years preceding enrollment, revalidation, or re-enrollment; or

(5) An exclusion or debarment from participation in a federal or state healthcare program.

CMS also will place the provider or supplier into the high screening level if an individual who maintains 5% or greater direct or indirect ownership interest in such provider or supplier has had a final adverse action imposed against it within the previous ten years.[14]

With regard to timing, CMS made clear that they will not wait until agency action is final before shifting a provider or supplier

into a new screening level.[15] Thus, if a provider or supplier is appealing an adverse determination noted above, CMS will still move the provider or supplier into the high-risk category despite pending appeals.

Level of Screening—Medicare

As in the Proposed Rule, in the Final Rule, CMS based the level of enrollment screening on the risk category to which a provider or supplier is assigned. We have included a revised chart showing some of the changes below—noting additions with underlined text and deletions with a ~~strikethrough~~—*See* Figure 2 below.

In the Final Rule, CMS combined the fingerprinting requirement with the background check requirement, and fingerprint-based criminal history record checks from the Federal Bureau of Investigation will be implemented sixty days following the publication of sub-regulatory guidance.[16] CMS removed the requirement present in the Proposed Rule that fingerprints be submitted solely on the FD-258 card, suggesting that electronic fingerprinting would be faster.[17] CMS made clear that the relevant individuals who are required to undergo a criminal history record check will incur the cost of having their fingerprints taken, while CMS will bear the cost of processing the fingerprint-based criminal history record check.[18]

In the Final Rule, CMS restricted its fingerprint-based criminal history record check requirement to individuals with a 5% or greater direct or indirect ownership interests.[19] CMS also removed tax delinquency from the list of database checks in the Final Rule, noting that although CMS has new authorities to obtain tax information as part of ACA and other recently enacted statutes, they are not prepared to operationalize those provisions at this time.[20]

As a final note on the new enrollment screening requirements, although the normal Medicare revalidation cycle remains three years for DMEPOS suppliers and five years for all other providers and suppliers, CMS can now require that a provider or supplier revalidate its enrollment at any time.[21] According to CMS, the new authority to conduct off-cycle validations of providers and suppliers will enable them to apply the new screening requirements to all currently enrolled providers and suppliers by the statutory effective date of March 23, 2013.

Screening Categories and Levels—Medicaid and CHIP

Because of the expense and efficiencies involved, CMS will allow states to rely on the results of the Medicare contractor's screening to meet the provider screening requirements under Medicaid and

Figure 2—Comparing Current Screening Requirements and Proposed Screening Requirements

Type of Screening Required (Medicare)	Current Rule	Proposed Rule—Limited	Proposed Rule—Moderate	Proposed Rule—High
Verification of any provider/supplier-specific requirements established by Medicare	X	X	X	X
Verification of license (may include licensure checks across states)	X	X	X	X
Database checks: • Social Security Number • National Provider Identifier • National Practitioner Data Bank licensure • HHS OIG exclusion • Taxpayer identification number • ~~Tax delinquency~~ • Death of individual practitioner, owner, authorized official, delegated official, or supervising physician	X	X	X	X
Unscheduled or unannounced pre-enrollment or post-enrollment site visits	Only DMEPOS and IDTFs pre-enrollment; ad hoc for others		X	X
Fingerprint-based Criminal History Record Check of law enforcement repositories—individual owners with 5% or more direct or indirect ownership, ~~authorized or delegated officials and managing employees~~				X

CHIP. Similarly, state Medicaid agencies can rely on the results of sister state Medicaid programs and CHIP.

With regard to the Medicaid and CHIP programs, CMS confirmed that for types of providers that are recognized as a provider or supplier under the Medicare program, states will use the same screening level that is assigned to that category by Medicare.[22] If limited risk, CMS requires the states to do the following: (1) verify that a provider meets any applicable federal regulations or state requirements for the provider type; (2) license verification; and (3) defined database checks.[23] If moderate risk, the states must do the following: (1) perform limited-risk screening; and (2) conduct on-site visits in accordance with 42 C.F.R. § 455.432.[24] If high risk, the states must do the following: (1) perform limited and moderate risk screenings; (2) conduct a criminal background check; and (3) require the submission of a set of fingerprints (§ 455.434).[25]

For those Medicaid and CHIP provider types that are not recognized by Medicare, states will assess the risk posed by a particular provider type. According to CMS, states can assess the risk of provider type themselves, but CMS expects states will assess the risk using criteria similar to those used in Medicare. For example, physicians, NPPs, medical groups, and clinics that are state licensed or state regulated would generally be categorized as limited risk.[26] Those provider types that generally are highly dependent on Medicare, Medicaid, and CHIP to pay salaries and other operating expenses, and that are not subject to additional government or professional oversight, would be considered moderate risk.[27] Those provider types identified by the state as being especially vulnerable to improper payments would be considered high risk.[28]

Medicaid and CHIP have a five-year enrollment revalidation period.[29] Under the new rules, CMS expects the state Medicaid agencies to complete the first revalidation cycle by 2015 with 20% of all providers being revalidated each year beginning 2011.[30]

In the Final Rule, under Section 455.410, CMS adopted the requirement from Section 1902(kk)(7) of the Social Security Act that states require *all* ordering or referring physicians or other professionals to be enrolled under a Medicaid state plan or waiver of the plan as a participating provider. CMS, however, did not expand the requirement to apply to risk-based managed care organizations.[31]

Application Fee

Institutional providers must pay the application fee (statutorily set at $500 for 2010 and adjusted yearly based on the Consumer Price Index for all urban consumers) with the submission of an initial enrollment application, an application to establish a new practice location, as part of revalidation, or in response to a revalidation request.[32] An "institutional provider" is broadly defined as "any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (not including physician and non-physician practitioner organizations), CMS-855S or associated Internet-based PECOS enrollment application."[33]

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The application fee is intended to cover both federal and state costs of the screening program.[34] The application fee is *not* linked to the risk level associated with the provider or supplier,[35] i.e., you do not pay more because you are at a high level versus a limited risk level.

The application fee is nonrefundable except if submitted with one of the following: (1) a request for hardship exception that is subsequently approved; (2) an application that is rejected prior to initiation of screening processes; or (3) an application that is subsequently denied as a result of the imposition of a temporary moratorium.[36] An application will be rejected and, in the case of revalidations, billing privileges may be revoked if the institutional provider does not submit the application fee or hardship exception.

A state may rely on the results of the Medicare screening requirements for participation in a state Medicaid program or CHIP, and a provider or supplier enrolled in more than one program (that is, Medicare and Medicaid or CHIP, or all three programs) would only be subject to the application fee under Medicare and that fee would cover screening activities for enrollment in all programs.[37] In the Final Rule, CMS stated that the operational logistics to implement this one-fee concept will be addressed in sub-regulatory guidance.[38]

CMS also finalized the provisions of the Proposed Rule with regard to the application fee with the following exceptions:[39]

- CMS added language to clarify that a provider or supplier may submit both an application fee and hardship exception to avoid delays in the processing of the application if the hardship exception is not approved at Section 424.514(a) and (b).
- CMS added language to clarify that if a provider submits a hardship exception request without an application fee, and CMS does not approve the hardship exception request, CMS will notify the provider or supplier and allow thirty days from the date of notification to submit the application fee at Section 424.514(h).
- CMS also added language that specifies that states must collect the applicable application fee from Medicaid-only and CHIP-only providers and suppliers at Section 455.460. The state in consultation with the HHS Secretary may waive the fee for Medicaid-only or CHIP-only providers if the state demonstrates that the imposition of the fee will impede beneficiary access to care.[40]

Temporary Moratoria on Enrollment

ACA Section 6401(a) allows the HHS Secretary to impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers if necessary to combat fraud, waste, or abuse under those programs.[41] CMS believes these moratoria give it a unique opportunity to develop new regulatory provisions and program incentives that will better ensure quality and prevent abuse.

Under the Final Rule, CMS may impose a temporary moratorium on enrollment of new Medicare providers and suppliers of a particular type or in a particular geographic area.[42] CMS may impose these moratoria if:

(1) CMS identifies a trend that signifies a high risk of fraud, waste, or abuse for a particular provider or supplier type or geographic area;[43]

(2) A state Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that also participate in Medicare; or

(3) In consultation with HHS, HHS OIG, or the U.S. Department of Justice (DOJ), CMS identifies either a particular provider or supplier type or a particular geographic area that appears to have significant potential for fraud, waste, or abuse.

The Final Rule emphasizes the HHS Secretary's broad authority to impose temporary moratoria under ACA. In addition, CMS may lift an imposed moratorium under the following circumstances:

(1) The president declares a disaster area under the Stafford Act;

(2) The circumstances that merited the moratorium have passed or CMS has imposed safeguards to address the identified risk;

(3) The HHS Secretary declares a public health emergency; or

(4) The HHS Secretary determines that the moratorium is no longer necessary.

State Medicaid agencies also must comply with federally imposed moratoria. In addition, a state Medicaid agency, in consultation with the HHS Secretary, may impose its own temporary moratorium, numerical cap, or other limit designed to mitigate risk of fraud or abuse to the Medicaid program.[44] Before imposing a temporary moratorium, however, the state agency must determine that the action would not adversely affect beneficiary access to Medicaid services and provide the HHS Secretary with written notice of all details of the moratorium. Under both the Medicare and Medicaid rules, moratoria initially will be imposed for six months, though if necessary, the period can be further extended in six-month increments.[45]

The Final Rule, in most respects, is consistent with the provisions in the Proposed Rule regarding moratoria. A few additions are worthy of note.[46] First, CMS added language to clarify that it will fully assess the impact of any temporary moratoria on beneficiary access to needed services. Second, CMS also added language to clarify that it will publish in the *Federal Register* both the imposition of a temporary moratorium, including the rationale and affected parties, and an announcement lifting the temporary moratorium. Third, CMS clarified that although the moratoria will apply to pending enrollment applications, those that have already been approved will not be impacted. Finally, CMS added the public health rationale for lifting a temporary moratorium at the request of public commenters.

Suspension of Payments

ACA Section 6402(h) permits the HHS Secretary to suspend payments to a provider or supplier pending investigation of a credible fraud allegation.[47] Under the Final Rule, CMS or a Medicare contractor may entirely or partially suspend payments to Medicare providers and suppliers if, after consultation with HHS OIG or DOJ, it identifies any "credible allegation of fraud."[48] Even if no fraud is suspected, CMS or the Medicare contractor also may suspend payments upon receipt of reliable information that Medicare has overpaid for services or if the provider has failed to file a timely cost report.[49] In all instances, CMS plans to evaluate the need for payment suspension on a case-by-case basis.

Despite credible fraud allegations, CMS may choose not to impose a payment suspension for good cause. Good cause may exist when:

(1) HHS OIG or other law enforcement officials specifically request that payments not be suspended to avoid jeopardizing an ongoing investigation;

(2) Beneficiary access to services may be so compromised as to endanger life or health;

(3) CMS or a Medicare contractor can implement other remedies that would more effectively protect Medicare funds; or

(4) CMS determines that a payment suspension is not in the best interest of the Medicare program.

CMS must re-evaluate payment suspensions every 180 days. In doing so, CMS will determine whether good cause exists not to continue the suspension and will request certification from law enforcement officials that the investigation is ongoing. CMS or the Medicare contractor will continue to withhold payment from a provider or supplier until the amount of overpayment is determined or, in cases involving credible allegations of fraud, until the investigation has been completed.[50] Good cause not to continue a payment suspension also will develop if a payment suspension has been in effect for eighteen months and the investigation has not been resolved, except where HHS OIG is considering the case or DOJ requests in writing that the suspension be continued.[51]

Similar rules apply to state Medicaid agencies, which *must* suspend Medicaid payments once the agency determines there to be a credible allegation of fraud[52] so long as no good cause[53] exists to avoid the suspension.[54] The state agency need not notify providers of its intent to suspend payment before taking action, but generally must send notice of the suspension within five days, though it may wait up to ninety days if law enforcement so requests.[55]

Once the Medicaid agency seeks to initiate a payment suspension, it must make a written referral to the Medicaid fraud control unit (MFCU) or, if no formal unit exists, to an appropriate law enforcement agency. If the MFCU or other investigator declines to accept the referral, the agency must discontinue the payment suspension. The state Medicaid agency also must document notices of suspension, fraud referrals to law enforcement, quarterly certifications of continuing investigation, and notices of termination of the payment suspensions for a period of five years.[56] The agency must similarly document and retain records of instances when good cause prevented the imposition of a payment suspension. Finally, the agency must make an annual report to the HHS Secretary that details any payment suspensions, the nature of suspected fraud and outcome of resulting investigations, and any situations where good cause not to suspend payments existed in cases where there was reliable evidence of fraud.

The provisions regarding suspension of payments in the Final Rule are substantially similar to those published in the Proposed Rule, with a few minor additions. These include the good-cause provision for discontinuing payment suspensions that have been in effect for eighteen months and a statement clarifying that the Medicaid agency may continue a payment suspension even if the MFCU declines to accept a referral if the state has alternative federal or state authority to do so.

Compliance Programs

ACA Section 6102 requires nursing facilities to have effective compliance and ethics programs to detect fraud and promote quality of care. CMS solicited comments in the Proposed Rule regarding future requirements for ethics and compliance program provisions.[57] As indicated in the Proposed Rule, CMS did not publish a final rule on these requirements. It intends to do further rulemaking and will provide more specific proposals at a future date. Comments received during the comment period will be considered in constructing these requirements.

Effect of Other Program Terminations

ACA Section 6501 requires that a state Medicaid program terminate any provider whose participation in Medicare, Medicaid, or CHIP has been terminated in another state.[58] The ACA provisions emphasize that states must notify other states when a provider is terminated in order to prevent other states from becoming vulnerable to fraud or abuse. CMS is currently establishing a web-based portal through which states will be able to easily access informa-

tion about terminated providers.[59] CMS requests that states report terminations monthly in order to help other programs protect themselves from increased risk. State law will dictate when terminated providers are eligible to seek re-enrollment.[60]

Under the Final Rule, state Medicaid agencies must deny or terminate the enrollment of any provider that is terminated from the Medicare program or from another state's CHIP or Medicaid program on or after January 1, 2011, unless the agency provides a written determination that termination or denial is not in the best interests of the state's Medicaid program.[61] In order for this requirement to apply, however, the program termination must be "for cause," rather than based on a voluntary action by the provider or supplier.[62] To be considered "terminated," the program must have taken action to revoke the provider, supplier, or eligible professional's billing privileges, and the provider must have exhausted all appeal rights or let the timeline for appeal expire.[63]

The provisions in the Final Rule are substantially similar to those in the Proposed Rule. The only addition was a clarification that the requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had billing privileges revoked for cause, which the Final Rule states may include, but is not limited to fraud, integrity, or quality.[64]

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1 Pub. L. No. 111-148 (eff. Mar. 23, 2010), as amended by Pub. L. No. 111-152 (eff. Mar. 30, 2010).
2 76 Fed. Reg. 5862 (Final Rule, Feb. 2, 2011).
3 76 Fed. Reg. at 5865 - 5907 (to be codified at 42 C.F.R. § 424.518 for Medicare providers and suppliers; 42 C.F.R. § 455.400 *et seq.* for Medicaid providers; and 42 C.F.R. § 457.990 for CHIP providers).
4 76 Fed. Reg. at 5891.
5 76 Fed. Reg. at 5883-85.
6 *Id.* at 5884.
7 *Id.* at 5884-85.
8 "Limited" risk category also includes histocompatibility laboratories; Indian health service facilities; mammography screening centers; organ procurement organizations; mass immunization roster billers; religious nonmedical healthcare institutions; rural health clinics; radiation therapy centers; competitive acquisition program/Part B vendors; and dentists ~~;and public or government owned or affiliated ambulance services suppliers.~~
9 "Moderate" risk category also includes community mental health centers; and ~~nonpublic, nongovernment owned or affiliated~~ ambulance services suppliers.
10 *Id.* at 5880.
11 *Id.* at 5876.
12 75 Fed. Reg. 58204, 58212 (Proposed Rule, Sep. 23, 2010) (codified at 42 C.F.R. § 424.518(c)(3)).
13 76 Fed. Reg. at 5877, 5894.
14 *Id.* at 5877.
15 *Id.* at 5889.
16 *Id.* at 5872, 5876. CMS continues to seek guidance regarding certain aspects of the fingerprinting requirement.
17 *Id.* at 5879.
18 *Id.* at 5890.
19 *Id.* at 5882 (CMS eliminated the following individuals from the fingerprint-based criminal background checks: officers, directors, and managing employees—to the extent that they do not have a 5% or greater ownership interest.); *see* 42 C.F.R. §§ 455.434(b)(2); 457.990 (CMS also applied the change to Medicaid and CHIP.).
20 *Id.* at 5875.
21 42 C.F.R. § 424.515(e).
22 76 Fed. Reg. at 5895.
23 42 C.F.R. § 455.450(a).
24 *Id.* § 455.450(b).
25 *Id.* § 455.450(c).
26 76 Fed. Reg. at 5895.
27 *Id.* at 5895-96.
28 *Id.* at 5896.
29 42 C.F.R. §§ 455.414; 457.990.
30 76 Fed. Reg. at 5901.
31 *Id.* at 5904.
32 42 C.F.R. § 424.514.
33 *Id.* § 424.502.
34 76 Fed. Reg. at 5915.
35 *Id.* at 5912-13.
36 42 C.F.R. § 424.514(d)(2)(v).
37 76 Fed. Reg. at 5916.
38 *Id.*
39 *Id.* at 5917.
40 *Id.* at 5916.
41 *Id.* at 5917.
42 *Id.* at 5965 (to be codified at 42 C.F.R. § 424.570). Temporary moratoria will not apply to changes in practice location, ownership, or provider or supplier information. They also will not apply to enrollment applications that have been approved, but not yet formally entered into the system.
43 Examples of potential trends include a highly disproportionate number of providers or suppliers relative to the number of beneficiaries in an area or a rapid increase in enrollment applications in a particular category. *Id.*
44 *Id.* at 5970 (to be codified at 42 C.F.R. § 455.470).
45 *Id.*; 76 Fed. Reg. 5965 (to be codified at 42 C.F.R. § 424.570).
46 *Id.* at 5928.
47 *Id.*
48 *Id.* at 5961 (to be codified at 42 C.F.R. § 405.371). A "credible allegation of fraud" may come from any source, including, but not limited to: (1) fraud hotline complaints; (2) claims data mining; (3) patterns identified through audits, false claims cases, or law enforcement investigations. *Id.* (to be codified at 42 C.F.R. § 405.305). To be credible, the allegation must have sufficient "indicia of reliability." *Id.* at 5961 (to be codified at 42 C.F.R. § 405.371).
49 *Id.* at 5961-62 (to be codified at 42 C.F.R. § 405.371).
50 *Id.* (to be codified at 42 C.F.R. § 405.370). An investigation will be considered resolved when legal action is terminated by settlement, judgment, or dismissal or when the case is dropped because of insufficient evidence. ***Id.***
51 *Id.* at 5961 (to be codified at 42 C.F.R. § 405.370(b)(3)).
52 CMS did not set forth a definition of what constitutes a "credible allegation of fraud" for purposes of the Medicaid requirement, asserting that states instead should retain the flexibility to determine their own definitions consistent with state law. *Id.* at 5935.
53 The good-cause provisions are substantially similar to those under the Medicare Rule. *Id.* at 5966-67 (to be codified at 42 C.F.R. § 455.23).
54 *Id.* at 5966.
55 Notice must: (1) state that payments are being suspended in accordance with the CMS rules; (2) set forth the general allegations supporting the suspension; (3) state that the suspension is temporary; (4) specify the types of claims or business units for which the suspension is effective; (5) inform the provider of the right to submit written evidence to the state Medicaid agency; and (6) notify the provider of its right to the administrative appeals process and the applicable state law governing that process.
56 76 Fed. Reg. at 5967 (to be codified at 42 C.F.R. § 455.23).
57 *Id.* at 5942.
58 *Id.* at 5943.
59 *Id.* at 5944.
60 *Id.* at 5946.
61 *Id.* at 5968 (to be codified at 42 C.F.R. § 455.416). A provider's enrollment may also be terminated or denied if CMS or the state agency determines that the provider has falsified any of the information on the application or if either entity is unable to verify the applicant's identity. *Id.* at 5969 (to be codified at 42 C.F.R. § 455.416).
62 *Id.* If voluntary action is taken to avoid a sanction, however, the termination provision does apply.
63 *Id.* at 5967 (to be codified at 42 C.F.R. § 455.101).
64 *Id.* at 5946 (to be codified at 42 C.F.R. § 455.101(3)).

Healthcare Reform

Final Rule Update: CMS Extends Deadlines, Issues Clarifications on Redistribution of Unused Residency Slots Under PPACA

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Editor's Note:

The January 2011 edition of *The RAP Sheet* featured an analysis of the *proposed rule* on the redistribution of graduate medical education (GME) residency slots as mandated by healthcare reform. The following is an update based on the November 24, 2010, final rule. We greatly appreciate the author of the prior analysis providing this update as well.

On August 3, 2010, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule (Proposed Rule) providing proposed guidelines for the redistribution of unused residency slots under Section 5503 of the Patient Protection and Affordable Care Act (PPACA).[1] On November 24, 2010, CMS published a Final Rule (Final Rule) that largely adopted the provisions of the Proposed Rule discussed in our earlier article.[2] However, CMS made several changes in the Final Rule that should be noted.

In the Final Rule, CMS extended the deadline for hospitals eligible for an increase in the resident cap to submit their applications from December 1, 2010, to January 21, 2011.[3] Hospitals that were notified that they will be audited for possible cap reductions will have until March 1, 2011, to submit their applications.[4] In addition, CMS extended its own internal deadline by which Medicare contractors are to estimate the number of slots available for redistribution from May 1, 2011, to May 16, 2011.[5]

Changes with Respect to Resident Cap Reductions

The Final Rule clarifies that new teaching hospitals (i.e., those that do not yet have a resident cap established) as well as hospitals that have had a resident cap established during the last three cost reporting periods ending prior to March 23, 2010, are exempt from the cap reduction process.[6] With respect to rural hospitals with less than 250 beds, which are also exempt from the cap, CMS initially proposed to use bed count data from the most recent cost reporting period ending prior to March 23, 2010. Under the Final Rule, CMS will instead use data from the rural hospital's most recent cost reporting period ending prior to March 23, 2010, for which a cost report was submitted to the Medicare contractor prior to March 23, 2010.

With respect to hospitals that have recently merged, the Proposed Rule stated that hospitals that merged but were not merged in any of the three reference cost reporting periods would have their full-time equivalent (FTE) counts and caps combined for purposes of determining the cap reduction. In the Final Rule, CMS modified its proposal, noting that when two hospitals have merged, and those hospitals have three separate cost reporting periods that can be used to determine the hospitals' reference resident levels, CMS will determine the highest reference resident level and the otherwise applicable resident limit for each hospital separately. CMS will then combine the determinations of any excess slots to apply to the merged hospitals.[7]

Changes With Respect to Resident Cap Increases

The only hospitals eligible for an increase in their resident caps under PPACA are rural hospitals and urban hospitals located in a state with a resident-to-population ratio in the lowest quartile or in one of the ten states, territories, or districts with the highest proportion of their population living in a health professional shortage area. In the Proposed Rule, CMS discussed at length additional criteria that would be used to prioritize which hospitals receive cap increases. CMS proposed to prioritize hospitals applying for a redistribution by organizing them into five "priority categories" based on certain factors that applied to the hospitals. In the Final Rule, CMS reduced the number of priority categories to four and made other revisions.[8]

To apply for additional slots, the Proposed Rule provided that a hospital would have to provide documentation showing that it meets one of three "demonstrated likelihood criteria." In the Final Rule, CMS eliminated the third demonstrated likelihood criterion and incorporated it into the first two criteria. Thus, under the Final Rule, a hospital must meet one of two criteria in order to qualify for a cap increase: (1) the hospital intends to establish a new residency program that will begin training residents at some point during the first three cost reporting periods beginning on or after July 1, 2011, and does not have sufficient room under its current FTE cap to accommodate those residents or is already training in excess of its FTE cap; or (2) the hospital intends to use the additional FTEs to expand an existing program within the same three-year period and does not have sufficient room under its current FTE cap to accomplish the expansion *or* is already training residents in excess of its FTE cap.[9] In addition, CMS modified the documentation requirements that hospitals must meet in order to satisfy the demonstrated likelihood criteria.[10]

The Final Rule also clarified CMS' position concerning two statutory requirements: (1) that hospitals receiving cap increases must use at least 75% of any FTE increase in a primary care or general surgery residency during the five-year period from July 1, 2011, through July 1, 2016, and (2) that these hospitals ensure, for this same five-year period, that their number of FTE primary care residents does not fall below their average number of primary care residents during the three cost reporting periods ending prior to March 23, 2010. With respect to these two requirements, CMS stated that it believes it has "discretion to consider a hospital's performance over more than 1 year, rather than always reviewing each year during the 5 years."[11] Thus, if a hospital's

GME payments are reviewed during the first year of the five-year period, and the hospital is found not to have met the primary care average or the 75% threshold, then the hospital would lose the additional slots it received through the redistribution, and it would lose those slots permanently, even if the hospital was able to meet the requirements for a subsequent year.[12] However, if the hospital's GME payments were not reviewed in the first year of the five-year period, but are later reviewed in the third year of that period, and the hospital is found not to have met the primary care average or 75% threshold requirement, then rather than immediately removing the hospital's additional slots, the contractor could review the GME payments for the first two years and average the resident counts for all three years to determine if the hospital has met the criteria over a three-year period.[13] If the hospital has met the requirements for that three-year period, then the hospital would be able to keep the additional slots it received through the redistribution process.

Finally, CMS' Proposed Rule would have precluded hospitals that received additional resident slots through the redistribution process from using those slots as part of the aggregate cap in a Medicare GME affiliation agreement. In the Final Rule, CMS revised its proposal, stating that hospitals may use slots awarded through the redistribution process as part of a GME affiliation agreement after five years (i.e., as part of GME affiliation agreements for the academic year beginning July 1, 2016).

1 75 Fed. Reg. 46170, 46390-46421 (Aug. 3, 2010).
2 75 Fed. Reg. 71800, 72147-72212 (Nov. 24, 2010).
3 *Id.* at 72174.
4 *Id.*
5 *Id.* at 72153.
6 *Id.* at 72160.
7 *Id.* at 72165-72166.
8 *Id.* at 72182-72184.
9 75 Fed. Reg. at 72171-74.
10 *Id.*
11 *Id.* at 72200.
12 *Id.* at 72200-72202.
13 *Id.*

In Case You Missed It . . .

Starting with the January 2011 edition of *The RAP Sheet*, we added a new feature, referencing email alerts that have been issued by the Regulation, Accreditation, and Payment Practice Group (RAP PG) since the January 2011 issue. Additional email alerts may have been issued since *The RAP Sheet's* submission—these can be found on the RAP PG Email Alerts webpage.

- Eighth Circuit Reverses Summary Judgment in *Medcenter One v. Sebelius*, Based on Lack of Written Agreement to Support Reimbursement for Costs Incurred Through Residency Program (March 4, 2011)
- Recent Cases of Interest—*University of Washington Medical Center v. Sebelius, Ancora Psychiatric Hospital v. Sebelius* (February 23, 2011)
- Federal District Court in Florida Declares Individual Mandate Under the PPACA Unconstitutional (February 1, 2011)
- Federal Government Recovers Record $4 Billion in Healthcare Fraud—Healthcare Fraud and Abuse Control (HCFAC) Program Report dated January 24, 2011 (January 27, 2011)
- Significant Wage Index Ruling Issued by Court of Appeals—*Cape Cod Hospital v. Sebelius* (D.C.D.C. Jan. 14, 2011) (January 20, 2011)
- Three Important Regulation, Accreditation, and Payment Updates—(1) "CMS Proposes New Hospital Value-Based Purchasing Program"; (2) "CMS Opens Registration for EHR Incentive Programs"; and (3) "Supreme Court Issues Unanimous Opinion Upholding the Treasury Interpretation of FICA" (January 13, 2011)
- Two Important Regulation, Accreditation, and Payment Updates—(1) "Final Rule Establishes Permanent HIT Certification Program"; and (2) "'Voluntary Advanced Care Planning' Rescinded in Final Rule" (January 7, 2011)
- Two Important Regulation, Accreditation, and Payment Updates—(1) "CMS Issues Transmittal 828"; and (2) "CMS Issues Final Rule Establishing Performance Standards for Dialysis Facilities" (January 6, 2011)
- CMS Issues Advanced Notice of Proposed Rulemaking Regarding EMTALA's Application to Hospital Inpatients (January 3, 2011)

If you would like to volunteer to assist the RAP Practice Group in preparing email alerts, please contact the Practice Groups staff.

Chair's Corner

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> "There is a certain relief in change, even though it be from bad to worse; as I have found in traveling in a stage-coach, that it often a comfort to shift one's position and be bruised in a new place."
>
> —Washington Irving, *Tales of a Traveler* (1824)

Between Tunisia, Egypt, and Libya, this is clearly a time of change throughout the world, with ripple effects being felt everywhere from the gas pumps to the grocery store. In the almost twenty years that I have been practicing healthcare law, we have seen the rise and fall and rise again of physician hospital organizations (now recast as accountable care organizations (ACOs)), capitation (now recast as global payment systems), hospital physician integration, de-integration and now frenzied integration, and countless efforts to reform component pieces of the Medicare and Medicaid programs.

Where do we stand today?

I don't have the answers. By the time this publication hits your virtual desk, the first set of proposed regulations defining ACOs may have hit the street and formed the basis of countless webinars, publications, and legal alerts. Hospital C-Suites across America will have digested the rule to see whether their current or future ACO strategy appears to work, whether it needs to be re-tooled, or whether it makes sense at all.

New Medicare enrollment standards, as updated in this edition of *The RAP Sheet*, will have been implemented by the Centers for Medicare & Medicaid Services (CMS), requiring enhanced screening of the owners and operators of the entity, including fingerprinting and Federal Bureau of Investigation background checks based upon a three-tiered risk classification system. This remarkable and now-final rule highlights the serious program vulnerabilities that continue to exist around Medicare enrollment and the efforts that CMS is prepared to pursue to use enrollment as the key gatekeeper to Medicare billing and payment.

Home health agency (HHA), durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and independent diagnostic testing facility (IDTF) enrollment continue to be an area of significant program integrity concern for CMS. While revised HHA change of ownership rules will help lessen the impact of the prior thirty-six-month rule, as discussed in one of the articles in this issue, HHAs continue to receive enhanced scrutiny associated with change of ownership situations involving a change of the majority of owners of that HHA entity. IDTFs and other suppliers of advanced diagnostic imaging must soon meet new accreditation standards as a condition of Medicare payment. Meanwhile, DMEPOS suppliers have watched the full implementation of surety bond and accreditation requirements, revised and strengthened supplier standards, and the implementation of the first competitive bid roll-out.

While certain aspects of the Affordable Care Act (ACA) remain subject to potential funding constraints by a Republican-controlled House of Representatives or, potentially, broader repeal based upon the constitutionality of ACA itself, certain aspects of ACA appear to be taking firm root in many of the nation's largest healthcare systems. In particular, hospitals and healthcare systems increasingly are seeking to employ physicians, integrate with physicians, and engage physicians for service-line management relationships. The reasons for this progression are multi-faceted and market specific and yet, at every hospital board room across America, the terms "global payment" and "shared financial risk" have joined the dinner table.

This is a historic time of change in the world and in healthcare—make no doubt about it.

Thankfully, one thing that hasn't changed is the American Health Lawyers Association (AHLA). Well, that is not entirely true. AHLA has continued to grow and adapt to change—developing programs, producing content for its members, and developing new constituent groups based upon changes in the healthcare market, dynamic changes in law firm structures, and changes in healthcare laws. One thing that remains the same is the foundation of the Practice Groups. The Practice Groups are the lifeblood of AHLA. The Practice Groups provide each member with an opportunity to meet experts in the fields in which he or she is practicing or seeking to practice. The Practice Groups provide a forum for collegial interchange of information and a source of foundational support for your practice. Each Practice Group depends upon its members. Please consider joining us at an upcoming monthly teleconference—regularly scheduled for the first Wednesday of the month from 3:00–4:00 pm Eastern (email pgs@healthlawyers.org for dial-in information) or attend a RAP Practice Group-sponsored luncheon.

Please consider writing an article or email alert, or volunteer to speak on a webinar. Please join us in this year of dynamic healthcare change.

Best,

Barry Alexander

Now is the Time to Volunteer

Did you consider writing an article recently when you saw a compelling court decision come down or a new regulation pop up? Were you listening into an AHLA webinar and thought about your own idea for an AHLA webinar? Have you always been curious about volunteering for the Practice Groups, but never knew who to contact or how to get started?

If yes is the answer to one or more of these questions, all that you need to do is email pgs@healthlawyers.org indicating your interest in volunteering for the Practice Groups. Your email can be as general or as specific as you would like. We will find the right spot for you; we only need to know that you are interested.

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