Due to the large number of comments received (over 600), CMS removed most of its proposed changes to the EMTALA regulations from the Final Rule. CMS indicated that it will publish a separate final rule governing EMTALA in the future.

CMS Issues Final Inpatient PPS Rule

On August 1, the Centers for Medicare and Medicaid Services (CMS) released its final hospital inpatient prospective payment system (PPS) rule. The final rule (Final Rule) is notable for what it does not include: provisions related to the Emergency Medical Treatment and Labor Act (EMTALA) regulations were dropped, as was a proposed expansion of CMS’ transfer patient policy.

As discussed below, the Final Rule does include wage index and market basket updates, adding 0.2 percent to the proposed annual 2.75 percent payment rate increase, and provisions related to direct and indirect graduate medical education (GME) requirements, reopening of fiscal intermediary decisions, and treatment of new medical technology, among other things.

The Final Rule is effective October 1, 2002.

Impact on Health Care Entities

The Final Rule gives health care entities some breathing room with respect to CMS’ proposed changes to EMTALA, patient transfer policy, and patient and bed counting policy set forth in the Proposed Rule, all of which CMS intends to study in greater detail before regulating further. The Final Rule also provides for a small additional payment increase (though not likely significant given other offsetting provisions in the Final Rule) and indicates CMS’ willingness to take innovative approaches, such as establishing new DRGs and permitting add-on payments, to ensure the timely introduction of, and reimbursement for, new technology.

What the Rule Does

Market Basket and Wage Index Updates

The Final Rule includes a 2.95 percent payment increase for inpatient services, reflecting a 3.5 percent adjustment to the market basket estimate. CMS also accelerated the phase-out of certain costs paid outside of PPS (namely, costs related to GME and CRNAs) from the wage index calculation, removing 100 percent of such costs beginning in fiscal year 2003, rather than continuing with the fourth year of the five-year phase-out period. CMS justified the acceleration on its finding that the change would benefit the majority of labor markets in the country. CMS, however, postponed its decision on whether to include contracted indirect patient care labor costs in the calculation of the wage index, pending further analysis.

GME

The Final Rule clarifies certain GME provisions related to reimbursement for entities involved in affiliated groups (as defined below). Under applicable law, institutions that are members of the same affiliated group may elect to apply the FTE resident limit used for reimbursement on an aggregate basis. This policy gives hospitals flexibility in structuring rotations...
within a combined cap when they share residents’ time. An “affiliated group” is defined in the Final Rule as:

- two or more hospitals that are located in the same urban or rural area (as defined in 42 CFR 412.62(f)) or in contiguous areas and meet the applicable rotation requirement.³
- two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement and are jointly listed: (i) as the sponsor, primary clinical site or major participating institution for one or more programs as used in the most current Graduate Medical Education Directory, or (ii) as the sponsor or is listed under “affiliations and outside rotations” for one or more programs in operation in Opportunities, Directory of Osteopathic Postdoctoral Education Programs.
- two or more hospitals that are under common ownership and, effective for all affiliation agreements beginning July 1, 2003, meet the rotation requirement.⁴

The Final Rule also provides that a hospital may receive a temporary adjustment to its FTE cap, which is subject to averaging rules, to reflect residents added or subtracted because the hospital is participating in an affiliated group provided that:

- each hospital in the affiliated group submits an affiliation agreement (defined below) to the intermediary and to CMS no later than July 1 of the residency program year during which the affiliation agreement will be in effect.
- a rotation of residents among the hospitals participating in the affiliated group during the term of the affiliation agreement (a so-called cross-training relationship) occurs, such that more than one of the hospitals counts the proportionate amount of the time spent by the residents in their FTE resident counts (the rotation requirement).⁵
- the net effect of the adjustments on the affiliated hospital’s aggregate FTE cap for each affiliation agreement does not exceed zero.
- if the affiliation agreement terminates for any reason, the FTE cap for each hospital in the affiliated group reverts to the individual hospital’s pre-affiliation FTE cap.⁶

The Final Rule also defines an “affiliation agreement” as a written, signed, and dated agreement by responsible representatives of each respective hospital in an affiliated group that specifies:

- the term of the agreement (minimum term of one year) beginning on July 1 of a year⁷
- each participating hospital’s direct and indirect FTE cap
- the annual adjustment to each hospital’s FTE cap, for both direct GME and IME (positive adjustments to one hospital’s cap must be offset by negative adjustments to another hospital’s cap)
- the names of the participating hospitals and their Medicare provider numbers.

In the Commentary, CMS indicates that affiliation agreements may be long or short, provided they meet the requirements in the regulations. CMS also states that, although some modification of such agreements may be permitted, such as a change in the original distribution of the aggregate FTE cap, it would be “skeptical of modifications that deviate significantly from the original affiliation agreement,”⁸ for example, where more hospitals are added to increase the original aggregate cap.

Finally, the Final Rule reiterates longstanding Medicare policy prohibiting one hospital from claiming FTEs training at another hospital for IME and direct GME payment, even when the hospital seeking to claim the FTEs actually incurs the cost of training the residents at the other hospital.⁹ The Final Rule also includes provisions for determining the weighted average per resident amounts for hospitals that are new participants in the Medicare program.

Reopening Intermediary Decisions

In response to two recent court cases whose holdings conflict with CMS’ long-held interpretations, CMS affirmatively states in the Final Rule its authority to reopen
intermediary determination and hearing decisions on provider reimbursement. Specifically, in the Final Rule, CMS revises the reopening regulation, 42 CFR 405.1885, to comport with CMS’ positions: (i) that an intermediary’s duty to reopen under subsection (b) of the regulation arises only if specifically directed by CMS to reopen to ensure consistency with legal provisions, and (ii) that the intermediary’s discretion to reopen under subsection (a) and (c) of the regulation is subject to CMS’ authority to direct the “original jurisdiction” of its own contractor over reopening matters.

In the Commentary, CMS acknowledges that under 42 CFR 405.1885(a) an intermediary “may” reopen decisions (and maintains that intermediaries will continue to make most of the reopening decisions), but argues that the provision “neither states nor implies that [CMS] lacks the authority to direct the intermediary to reopen or not reopen a specific matter.” In support of its position that it has such authority over reopenings, CMS also cites its criteria in the Provider Reimbursement Manual that guide the intermediary’s reopening decisions in the absence of a particular CMS directive and notes that under general legal principles found in agency law, CMS has authority to direct the actions of its own agents (i.e., intermediaries) in all matters, including reopening decisions. Finally, CMS reiterates in the Commentary its belief that new CMS reimbursement policies normally apply on a prospective-only basis (again contradicting the recent court cases that appear to permit retroactive application).

New Technology

In an effort to keep pace with medical progress, the Final Rule permits payment for certain new technologies through both add-on payments and creation of new DRGs. Add-on payments are generally only appropriate if a new technology represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries and if the new technology that meets this clinical definition also is demonstrated to be inadequately paid otherwise under the DRG system. The special payment treatment is used until the DRG system can be adjusted to reflect the cost of the new technology. The Final Rule includes an add-on payment for Xigris, a new treatment for severe sepsis, but declines to give special payment treatment to three other new technologies that CMS determined do not meet the add-on payment criteria.

In the Final Rule CMS also takes the unusual step of establishing two new DRGs for drug-eluting coronary stents (i.e., stents coated with drugs designed to minimize formation of scar tissue in the artery). The new DRGs were established prior to FDA approval of the devices, based on evidence of the value of the new technology and likelihood of widespread use, although the Final Rule provides that payment only applies to discharges beginning April 1, 2003 to permit FDA time to make the expected approval. With respect to the establishment of these new DRGs, the Commentary notes that such determinations will not be commonplace:

We note that this unprecedented approach is in response to the unique circumstances surrounding the potential breakthrough nature of this technology. We anticipate that the vast majority of new technologies in the future will continue to be routinely incorporated into the existing DRGs.

Other

The Final Rule also includes provisions governing provider-based status, capital-related costs, and hospital and hospital units excluded from the inpatient PPS rules, which are not discussed in detail here.

What the Rule Does Not Do

EMTALA

Due to the large number of comments received (over 600), CMS removed most of its proposed changes to the EMTALA regulations from the Final Rule. CMS indicated that it will publish a separate final rule governing EMTALA in the future. The Final Rule, however, contains one EMTALA provision, clarifying that EMTALA only applies to hospitals. Specifically, the Final Rule deletes from existing regulations governing hospital outpatient departments and hospital-based entities the requirement that “if any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus,
and a request is made on the individuals’ behalf for examination or treatment of a medical condition, as described in [42 CFR 489.24, the antidumping regulations], the hospital must comply with the anti-dumping rules.”

Transfer Policy
CMS also dropped from the Final Rule a proposal to expand its transfer patient policy beyond the 10 DRGs to which it currently applies. Current transfer patient policy provides that in transfer situations, including transfers to post-acute settings, full payment is made to the final discharging hospital and each transferring hospital is paid a per diem rate for each day of the stay not to exceed the full DRG payment (for applicable DRGs) that would have been made if the patient was discharged without being transferred. CMS had proposed to expand the transfer policy to all DRGs or at least to those DRGs with high rates of transfer, thus reducing reimbursement in the case of patients transferred to certain post-acute facilities. As with EMTALA, CMS removed this proposal from the Final Rule because it could not respond appropriately to all the comments it received and desired further study of the need to reduce payments to reflect cost-shifting due to reductions in the length of stay attributable to early post-acute care transfers and the need to ensure that payment remains adequate to ensure effective patient care.

IME
Generally under PPS, hospitals that train residents in an approved GME program receive an additional payment, known as IME, for Medicare discharges, which reflects the higher indirect costs of operating a teaching hospital. In the Final Rule, CMS dropped a proposed provision related to counting beds for IME adjustments. CMS received many comments in opposition to the proposal and ultimately decided to address the issue later in a more comprehensive analysis of bed and patient day counting policies. Finally, the Final Rule also provides an exception to the resident-to-bed ratio cap when hospitals and/or residency programs close and other hospitals assume the training of the displaced residents.

Conclusion
Thus, the Final Rule contains annual payment updates, clarifies certain IME and GME requirements and indicates a willingness by CMS to take creative approaches to new medical technology. It does not, however, address the changes to EMTALA or to transfer policy set forth in the Proposed Rule, giving CMS and health care entities additional opportunity to review and comment on these changes.

Endnotes
2 The Final Rule also includes provisions related to rural hospitals, sole community hospitals and critical access hospitals, which are not discussed here.
3 The rotation requirement, as defined in 42 CFR 413.86(g)(7)(ii), requires that each hospital in an affiliated group have a shared rotational arrangement with at least one other hospital within the affiliated group, and all of the hospitals within the affiliated group must be connected by a series of such shared rotational arrangements. A “shared rotational arrangement” means a residency training program under which a resident participates in training at two or more hospitals in that program. 42 CFR 413.86(b). Pursuant to the Commentary, a “shared rotational arrangement” exists if residents rotate from one hospital to another at some point during the period of years required to complete training in a particular program. All hospitals within an affiliated group must be connected by a series of shared rotational arrangements; a continuous linear chain amongst hospitals is sufficient—all hospitals do not have to cross-train all residents.
4 According to the Commentary, due to the possibility of misinterpretation with respect to hospitals that previously affiliated themselves based on common ownership under the prior rule that did not explicitly state a rotation requirement, hospitals that so affiliated, but have not met or currently are not meeting the rotation requirement are not required to meet the requirement until July 1, 2003, the date of the first training year beginning after publication of the final regulation.
5 Importantly, no resident may be counted in the aggregate as more than one.
6 Several commenters objected to this provision, preferring an FTE cap redistribution upon affiliation termination, but CMS states in the Commentary that it chose the reversion policy to prevent abusive practices, such as the formation of affiliation agreements solely for the purpose
of obtaining permanent adjustments to FTE caps, particularly in the case of hospital closure. Temporary FTE cap adjustments are permitted under the Final Rule for hospitals that take on the training of displaced residents in the case of hospital closure.

CMS chose the July 1 date for ease of administration based on the premise that virtually all residency programs begin on July 1. According to the Commentary, an affiliation agreement may be for a term greater than one year, and may be automatically renewable as long as it meets the one-year term requirement.

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If applicable regulatory criteria are met, a hospital may count the time residents spend training in a nonhospital setting for IME and direct GME reimbursement. See 42 CFR 413.86(f)(4).

See Monmouth Medical Center v. Thompson, 257 F.3d 807 (DC Cir. 2001)(finding that a statement in a CMS ruling changing CMS' interpretation of the statute in response to circuit court precedent constituted a directive to the intermediary to reopen, notwithstanding an explicit directive in the CMS ruling that the change in interpretation only be applied prospectively); Bartlett Memorial Medical Center v. Thompson, 171 F. Supp. 2d 1215 (W.D. Okla. 2001)(concluding that a CMS ruling that prohibited intermediary reopening on a particular reimbursement issue improperly interfered with the intermediary's discretion over provider requests for reopening and ordering the intermediary to act on the provider reopening requests without regard to the CMS ruling).

Statutory caps on target amounts for these excluded hospitals (psychiatric, rehabilitation and long-term care) expire on September 30, 2002. These hospitals will generally be reimbursed on a reasonable cost basis, although rehabilitation and long-term care hospitals will be transitioned to prospective payments systems. The Final Rule also contains provisions related to reimbursement for critical access hospitals, which are not discussed here.

This same regulation, 42 CFR 412.105, is also used to determine the number of beds for other purposes, such as determining disproportionate share adjustments. In the Proposed Rule, CMS proposed a formula based on bed count and hospital occupancy rate to make the IME adjustment.
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