Welcome reductions

Final Rules to cut regulations for hospitals, health care providers

Regulations

By Adrienne Dresevic, Esq. and Stephanie Ottenwess, Esq.

On May 9, 2012, the Centers for Medicare and Medicaid Services (CMS) issued two final rules (Final Rules) aimed at reducing unnecessary, obsolete or burdensome regulations on hospitals and health care providers.

The Final Rules implement provisions from proposed rules issued Oct. 24, 2011. They are aimed at achieving the key goal of President Barack Obama's regulatory reform initiative by reducing unnecessary burdens on businesses and saving nearly $1.1 billion across the health care system in the first year and more than $5 billion over five years. The Final Rules become effective July 16, 2012.

Regulatory Reform Rule

The Medicare Regulatory Reform Rule (MRRR) addresses Medicare regulatory requirements more broadly and eliminates duplicative, overlapping, and outdated requirements for health care providers.

In addition to many other changes, the MRRR creates an exception, in certain circumstances, to the existing automatic mandatory re-enrollment bar provisions in current regulations.

Specifically, under current regulation, a health care provider who has had its billing privileges revoked from participating in the Medicare program is automatically precluded from re-enrolling from the effective date of the revocation until the end of the re-enrollment bar (i.e., a minimum of one year but not greater than three years).

Under the MRRR, this automatic re-enrollment bar is eliminated in instances where providers have had their billing privileges revoked solely for failing to respond timely to a CMS revalidation request or other request for information.

Importantly, however, CMS made clear that this new exception will not prevent CMS' ability to combat fraudulent activity with respect to providers who fail to respond once or repeatedly to a revalidation or informational request.

Notably, notwithstanding this new exception:

- CMS maintains the discretion to revoke billing privileges under certain circumstances;
- CMS may deactivate (rather than revoke) the billing privileges of non-compliant providers; and
- CMS will closely scrutinize any provider seeking to reactivate its billing privileges or re-enroll in Medicare after a revocation under higher screening standards.

This exception is important and timely as CMS is engaged in its massive enrollment revalidation effort through 2015 — sending out notices to all providers currently enrolled in Medicare requiring them to revalidate their enrollment information with CMS under new tougher screening controls designed to prevent fraud.

Notably, however, this exception will not be applied retroactively. Moreover, fitting within the exception will not eliminate all adverse consequences for non-compliant providers. As such, providers and suppliers should continue to be diligent and with respect to responding timely to revalidation notices or other information requests from CMS.

Revisions to Conditions of Participation

By way of background, CMS has established specific regulatory requirements, Conditions of Participation (CoPs), that a hospital must meet in order to participate in Medicare.

The Final Rule makes a significant revision to the Medical Staff CoP by broadening the concept of the "medical staff." Notably, the Final Rule differs significantly from the proposed rule which would have added language to clarify that a hospital may grant privileges to both physicians and non-physicians to practice within their state's scope-of-practice law, regardless of whether they also are appointed to the hospital's medical staff.

There were more than 1,700 comments in response to the proposed rule, the vast majority of which were in opposition to the revisions.

Opposing commenters objected to allowing a hospital to grant privileges to a practitioner without requiring membership on the medical staff, which could polarize those on the medical staff versus those who are not, and could undermine the medical staff's chief function: self-governance.

It would give hospitals the opportunity to privilege practitioners outside the authority of the medical staff, which could have a negative impact on peer review of physicians in hospitals and could leave those not on the medical staff without the due process protections of peer review accorded to members of the medical staff.

Opposing commenters also objected to what they saw as "CMS' explicit endorsement of the replacement of physicians with non-physician practitioners ..." and what they saw as CMS' explicit encouragement of the expansion of scope of practice laws by states.

Considering these comments, CMS revised this provision to allow a hospital's governing body the greatest flexibility in determining which categories of non-physician practitioners that it chooses to be eligible for appointment to the medical staff.

In fact, CMS specifically states that the rule is "intended to encourage hospitals to be inclusive when they determine which categories of non-physician practitioners will be eligible for appointment to their medical staff."

Once these eligible categories are determined by the governing body, the Final Rule directs the medical staff to examine the credentials of all eligible candidates and make its recommendations for medical staff appointments to the governing body in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations.

Finally, any candidates appointed to the medical staff must be granted all of the privileges, rights, and responsibilities accorded to the appointed medical staff members.

Thus, although the final version of the rule does encourage hospitals to include non-physicians as eligible members of their medical staffs, it preserved the autonomy of the medical staff and maintained the physician supervision standard over non-physician practitioners.

There were many comments submitted suggesting additional regulatory changes aimed at reducing unnecessary, obsolete, or burdensome regulations that CMS acknowledged but deferred for possible future rule making.

Thus, providers and suppliers should remain attentive for future revisions to existing regulations.

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Expert not required to identify records reviewed for affidavit

Affidavits of Merit

By Brian Frasier, Esq.

A doctor's misidentification of the records he reviewed for a plaintiff's affidavit of merit (AOM) didn't invalidate the AOM, the Michigan Court of Appeals ruled.

The panel in *Kalaj v. Khan* (Lawyers Weekly No. 07-77659, 6 pages) said the affidavit of merit statute, MCL 600.2912d, doesn't require the doctor to specifically identify the documents reviewed in determining whether the treating doctor breached the standard of care.

The opinion is a straightforward interpretation of the AOM statute, said McKeen & Associates PC attorney Ramona Howard, who represented the plaintiff in the case.

"Quite frankly, the statute clearly says that you only have to review what you're provided," she said. "I presume that if an expert is given records that are insufficient to form an opinion, he would say so and ask for more. The onus is on the expert to say that. 'I can't give an opinion based on what you've given me.'"

In *Kalaj*, the expert was supplied X-rays marked as the ones that plaintiff was alleging were misread by the defendant and identified them as such in the affidavit. During discovery, it was learned that the X-rays were actually ones taken nine days later.

The defendant's attorney, Brian Doren of Plymouth, said the statute only specifically requires the expert review the complaint, the notice of intent (NOI), and medical records provided by the plaintiff.

"My point in the argument was that, if you're going to review anything, number one, you should actually review what you say you reviewed," he said. "And number two, although the statute doesn't specifically say it, it would be implied that you'd have to review the records that are the subject of alleged malpractice."

Doren said his argument isn't that an expert can only make such a determination with the X-rays, but that this expert said he looked at the specific X-rays that were alleged to have been misread when he actually didn't — meaning he lacked the foundation to form an opinion on whether the defendant breached the standard of care.

The court found that the doctor's misidentification of the X-rays wasn't relevant to reviewing the AOM, because the statute doesn't require that he identify what he reviewed for the purposes of forming his opinion that the defendant violated the standard of care.

"Arguably, taking it to its absurd logical extreme, he could look at medical records pertaining to you and offer standard of practice testimony as to a claim that I would be making," Doren said.

Sommers Schwartz PC attorney Robert Sickels said the court simply found that the time to fight the weight and credibility of the expert's opinion based on the later X-rays is at trial, and not when reviewing the sufficiency of the AOM.

"As a threshold matter, it's conceivable that a radiologist could opine that the defendant radiologist committed malpractice based on circumstantial evidence or other evidence that there must have been a misdiagnosis," he said.

"Certainly not having the films available is a problem for the plaintiff, but the court is saying that the expert who signed the affidavit could render an opinion in the absence of the actual films if there was other circumstantial evidence that could help him render an opinion, such as other film."

Sickels agreed with Howard that the court's decision is a rational interpretation of the AOM statute.

"I think the statute as written, which may have some deficiencies, requires that the experts say that I reviewed the medical records provided to me by the plaintiff concerning the allegations in the notice. The statute doesn't say that I've reviewed all available records."

Doren said no decision has been made on whether to file for leave to appeal to the Supreme Court.

If you would like to comment on this story, please contact Brian Frasier at (248) 865-3113 or brian.frasier@mi.lawyersweekly.com.

Decision in a Nutshell

The Case: *Kalaj v. Khan* (Lawyers Weekly No. 07-77659, 6 pages).

The Facts: The plaintiff's expert misidentified the source of X-rays he reviewed for the affidavit of merit.

The Decision: MCL 600.2912d doesn't require the doctor to specifically identify which records he reviewed in making the affidavit of merit, so an accidental misidentification doesn't invalidate the affidavit.

From the Decision: "[B]y its plain language, MCL 600.2912d(1) requires only 'that the health professional has reviewed the notice and all medical records supplied to him or her by the plaintiff's attorney concerning the allegations contained in the notice.' There is no specific requirement *which* hospital or medical provider's records must have been reviewed in order for the expert to ascertain a breach of the standard of care. Nor does the statute require that the health professional even identify the medical records he has reviewed. It is sufficient, under the plain language of the statute, for the expert to indicate that he has reviewed the records provided to him by plaintiff's counsel and that based on those records, he is willing and able to opine as to the defendant's negligence consistent with the elements set forth in the statute. Thus, [diagnostic radiologist Stuart] Mirvis was not required to review [defendant Basha Diagnostics'] films at all; that he mistakenly identified films provided to him as being the Basha films likewise does not render the affidavit of merit deficient under the statute, unless the absence of those films precludes him from opining that defendants breached the applicable standard of care by failing to diagnose plaintiff's spinal fracture on July 31, 2006. In such case, it would be up to Mirvis to indicate that his opinion, as set forth in the affidavit of merit, was no longer supported. He has not done so."