Dissecting Federal Regulation Processes: Delays Accompany the Rulemaking Process for ICD-10-CM/PCS, HITECH Act

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While the entire healthcare community has been waiting on the Department of Health and Human Services (HHS) for word on the ICD-10-CM/PCS delay, AHIMA staff have received a number of questions regarding the federal government's process for proposing, finalizing, or changing regulations. While there is some variance in how HHS and its agencies might deliver instructions, the approach to new or revised regulations is fairly standard.

Regulations usually begin in legislation-an act passed by Congress and signed by the President. Legislation can be very specific, but it can also be vague, which allows the specific federal department or agencies considerable latitude in writing the regulation itself. Legislation also often sets the timeline for a regulation's final effective date; however, these dates are not always met. In the long-awaited final omnibus rule for the HITECH Act upgrades to HIPAA, for instance, a delay was added to the final rule in early July.

A rule that proposes a change will often go through a discussion period involving the healthcare community and government. For example, the National Committee for Vital and Health Statistics often holds hearings on potential rules, providing the secretary of HHS with recommendations for future rules. The Health IT Policy and Standards Committees likewise serve as the advisors to the Office of the National Coordinator for Health IT, who in turn informs the HHS secretary and other agency heads of possible or potential regulations. More recently, several of the HHS agencies and offices have begun to use requests for information as a means of gathering information to help focus their proposals, such as the request for information issued to collect opinions on Nationwide Health Information Network governance-the means of overseeing the nationwide health information exchange networks. ONC will use the responses to this request to form a proposed rule.

Trajectory of an NPRM

Notices of proposed rulemaking (NPRMs) are typically developed by an agency or office, and then receive approval by the administrator of that office and the secretary of the responsible federal department. Following these initial steps, the NPRM is then sent to the White House's Office of Management and Budget (OMB), where the proposal is reviewed for a number of different financial, legal, and political perspectives.

When a rule of any kind goes to the OMB, it is posted on the OMB Web site, www.reginfo.gov/public/. The time OMB takes to review the NPRM varies considerably because OMB reviews all rules from all federal departments. A review can take weeks or months, and-as healthcare professionals have seen recently-a rule may be on the list for months only to disappear because it has been sent back to the agency or office for reasons unknown to the public. Often, even the agency or office is not told why a rule is hung up in OMB review.

If a rule makes it through the OMB process, the agency or office then posts what is called a "display copy" on its Web site. This copy is usually an unedited word document that does not include specific dates, such as due dates for comments or effective dates. This display copy is often very hard to read, but provides early access to the content of the rule.

In the next step, the government printing office provides the necessary editing and publishes the rule in its *Federal Register*, accessible online at www.federalregister.gov. This step marks the rule's official publication, which is the date that starts the clock on the sequence of deadlines that follows.

Public Comments Encouraged

NPRMs usually provide a comment period of either 30 or 60 days. While the days are calendar days rather than business days, when a due date falls on a weekend or holiday it is extended to the next federal government business day. The agency or office determines the response timeframe, basing the decision on factors such as level of controversy or need for timeliness. Though responses may be sent to the agency in a number of ways, the predominate submission method is electronically over the Internet. Responses are also posted for public review.

The time it takes for a complete review of the responses to the rule varies depending on the detail of the rule as well as overall interest in the rule. For instance, responses to the original HIPAA privacy rules numbered well over 50,000. The agency or office must consider all comments, but seldom specifically identifies a responder to the public. Comments are pooled for consideration and response.

The agency or office takes the comments for consideration and develops a description of the particular group, how it accepts or rejects the comments made, and the impact it will have on the rule. These comments and responses often make up most of the verbiage in the final rule. The rule itself is displayed at the end of the notice in a legal form.

Once the agency has completed its review and decision-making regarding a NPRM, it then goes through a process similar to the NPRM. It must be noted that it is not unusual for an agency or office to sit on a final rule for months or years. In recent administrations there has been some attempt to stipulate that if an agency or office does not publish a final rule within three years of its NPRM due date, it must issue another NPRM. With the healthcare environment changing so rapidly, three years is much too long to presume that all factors in the rule are the same.

Opposite of the long delays are the more routine considerations such as the Medicare Inpatient Prospective Payment System (IP-PPS) NPRM that usually comes out in May or late April, receives comments until the end of June, and publishes a final rule around the beginning of August. This timing is key, since the effective date must be October 1 of the same year. These dates will slip on occasion, but the effective date remains the same for routine business.

Finally, a Final Rule

As noted, a final rule goes through the same process as an NPRM. However, on occasion, the agency or office proposes a final option to the administrator who in turn forwards a recommendation to the secretary. The secretary may have to review the rule with White House officials. It is possible that the ICD-10 delay is one of these cases. The rule could be returned for further revisions at each point, in which case the process repeats. Once this process is complete, the rule goes again to OMB for review. When passing HIPAA in 1996, Congress also added an additional review period stating that a HIPAA rule or modification cannot be effective until 60 days after it is published in the Federal Register. These extra days are meant to give Congress the time to review the rule and take action if necessary. Congress has not exerted this right, but the HIPAA rules, whether final or proposed, have often been the exception to this entire process.

Occasionally, an agency or office might issue an "interim final rule." This occurs when there are still questions pertaining to all or sections of the rule for which the agency wants additional input. The rule becomes effective, but the notice signals that there may be future changes due to the input being requested.

There are many parameters in place that govern the rulemaking process. However, this process is not always followed, leaving AHIMA's advocacy and policy staff and others in the industry and government guessing as to the final effective date. Politics continues long after a law is passed, complicating the overall rulemaking process.

Our Current Standing

As of press time, the industry awaited final rules on ICD-10 compliance, the HITECH Act omnibus HIPAA change requirements, and several other requirements associated with ARRA-HITECH. While these delays can be frustrating, the AHIMA staff remains vigilant in its pursuit of any information they can provide to AHIMA membership on final or interim rules.

AHIMA staff encourage everyone to continue sending in comments on proposed regulations. HIM professionals have experienced significant favorable changes in rules due to comments, and only you can provide the detailed information needed as rules are developed and changed.

Keep those comments coming to both the federal government and AHIMA, and when you can, join one of AHIMA's comment teams or volunteer to sit on one of AHIMA's practice councils.

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Correction

The Word from Washington column "Red Light, Green Light, Red Light" that appeared in the June *Journal of AHIMA* incorrectly named the International Health Terminology Standards Development Organisation (IHTSDO). The *Journal* regrets the error.

Article citation:
Rode, Dan. "Dissecting Federal Regulation Processes: Delays Accompany the Rulemaking Process for ICD-10-CM/PCS, HITECH Act" *Journal of AHIMA* 83, no.9 (September 2012): 18-20.