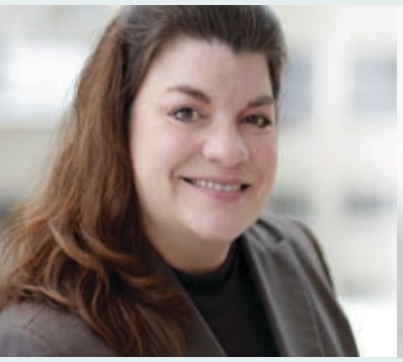
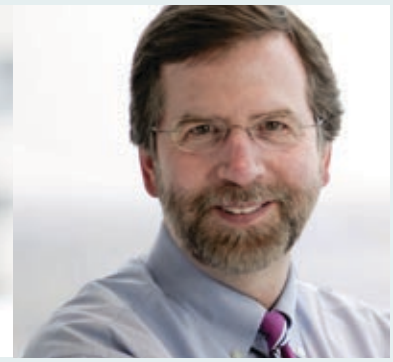
FALL 2011

# CORRIDORS

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





## General Assembly Regulates the Regulators

*by Pam Scott and Tom West*

The North Carolina General Assembly's historic 2011 session included sweeping reforms to curtail the regulatory authority of state agencies, including the Divisions of Health Service Regulation; Environmental Health; Mental Health, Developmental Disabilities, and Substance Abuse Services; and professional licensing boards and other agencies directly affecting the operation of hospitals in our state. The new rules of the regulating game put in place by legislators will significantly impact both regulators and hospitals and other businesses that work with them. Although the details have garnered little attention to date, perhaps the most important across-the-board developments affecting regulation by North Carolina agencies are the changes to our state's rulemaking framework that take effect October 1, 2011.

### New Rulemaking Framework—Focus on Economic Impact of New Rules

As part of a bill commonly known as the Regulatory Reform Act (SL 2011-398), the General Assembly enacted new statutes and amended existing statutes to rein in the discretion of agencies to enforce existing rules and adopt new rules. A common thread interwoven throughout these changes is a heightened focus on economic impact. One of the most significant revisions is a new requirement that prohibits agencies from adopting a new rule that will have an aggregate financial impact of $500,000 or more in a 12-month period, unless the rule is required to respond to (a) a serious and unforeseen threat to public health, safety or welfare; (b) an act of the General Assembly or U.S. Congress that specifically requires the agency to adopt rules; (c) a change in federal or state budgetary policy; (d) a federal regulation; or (e) a court order. Given the relatively low economic impact threshold that will trigger these new rulemaking constraints, these limitations will likely apply to the majority of new rules of any substance. The new $500,000 economic impact floor is a substantial reduction of the $3 million level that existed under the prior law.

Additional new fiscal-related requirements for agency rulemaking include:

- A mandate that the agency consider at least two alternatives before adopting a rule with an economic impact of $500,000 or more per year and explain why those alternatives were rejected;
- A requirement that the agency proposing a rule prepare any required fiscal note for approval by the Office of State Budget and Management (OSBM);
- Provisions for increased critical review and analysis of any fiscal note prepared for a proposed rule;
- A requirement that for a proposed rule with an economic impact of $500,000 or more per year, the agency must, among other things, (a) describe the persons who would be subject to the proposed rule and the types of expenditures those persons would have to make; and (b) estimate additional costs that would result from implementation of the proposed rule, including both economic and opportunity costs; and
- Provisions to facilitate public comment and input on a fiscal note regarding the economic impact of a proposed new rule.

### Other New Rulemaking Mandates

Along with these changes keyed to economic impact, the General Assembly established a slate of principles for all proposed new rules. These general rulemaking principles provide:

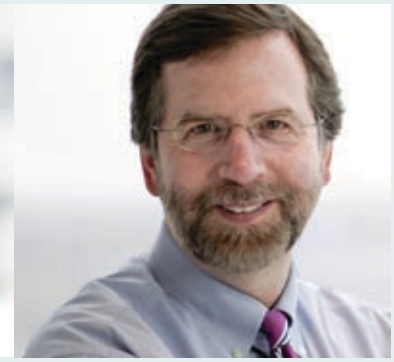
1. An agency may adopt only those rules that are expressly authorized by federal or state law and that are necessary to serve the public interest;
2. An agency must seek to reduce the burden on persons and entities that will have to comply with the rule;

*continued on page three*

p.s. Poyner Spruill LLP
ATTORNEYS AT LAW

WWW.POYNERSPRUILL.COM

301 Fayetteville St., Suite 1900, Raleigh, NC 27601/P.O. Box 1801, Raleigh, NC 27602-1801 P: 919.783.6400 F: 919.783.1075



# The End of the Agency's Second Bite at the Apple

*by Pam Scott and Tom West*

"It ain't over 'til it's over." Since the inception of North Carolina's Administrative Procedure Act (APA) over 30 years ago, the state's executive branch agencies have been able to live by this famous Yogi Berra adage because, in most instances, they had the final say in cases challenging their actions or decisions. But no more. As part of the General Assembly's regulatory reforms in the 2011 session, legislators took this final decision authority away from the agencies (with the exception of occupational licensing board cases) and gave it instead to administrative law judges (ALJs) in the state's Office of Administrative Hearings. This change will have important legal and practical ramifications for future cases that challenge an agency's decision or action that impacts hospitals or other regulated businesses.

Under the APA, a contested case challenging an agency's decision or action historically has been heard by an ALJ who is not a part of the agency being challenged. After hearing and considering the factual evidence and legal arguments of the parties, the ALJ would determine whether the agency decision or action at issue was correct. However, the ALJ's decision has not been final, but rather has been a recommendation sent back to the agency whose decision or action was being challenged, for a final decision.

For many years, some advocates for businesses and persons regulated by state agencies ridiculed this procedure as being a bit like the fox guarding the henhouse. On the other side, agencies maintained it was appropriate for them to have the final say due to their expertise in the area of law at issue and their delegated role as interpreter and enforcer of that law. The political climate was ripe in the General Assembly's 2011 session for the final decision authority to be transferred to ALJ's.

Beginning with contested cases filed on January 1, 2012, the ALJ's decision will be final, subject to an appeal to court by the agency or the person or business challenging the agency's action. This new rule will apply to all executive branch agencies and all types of contested cases subject to the APA. Unlike past APA amendments aimed at strengthening the weight and force of an ALJ's decision, there is no carve out for certificate of need disputes from this momentous change.

With the transfer of final decision authority to ALJs, it will be crucial for an agency and any businesses aligned with an agency in a contested case to put forth evidence establishing the agency's expertise and supporting the decision or action that is being challenged. Likewise, debunking the agency's analysis or approach in the action at issue through evidence presented on the record will be key to laying the foundation for an ALJ decision to reverse the agency's initial decision or action. With the elimination of the agency final decision, any appeal will be from the ALJ's decision, which means agencies and private parties aligned with agencies will not be so easily able to argue and rely on agency expertise as they have in years past, unless that expertise is established in the contested case record.

Pam Scott may be reached at 919.783.2954 or pscott@poynerspruill.com.
Tom West may be reached at 919.783.2897 or twest@poynerspruill.com.

POYNER SPRUILL IS GOING GREEN **In an effort to be more environmentally conscious, we also issue Corridors by email. To sign up for an email subscription to Corridors, please send an email request to alerts@poynerspruill.com with Corridors in the subject line. Save a tree!**

## General Assembly Regulates the Regulators continued from page one

3. Rules must be written in a clear manner and must be reasonably necessary to implement or interpret federal or state law;
4. An agency must consider the cumulative effect of all its rules related to the specific purpose for which the new rule is proposed and cannot adopt a rule that is unnecessary or redundant;
5. When appropriate, rules must be based on sound and reasonable scientific, technical, economic, and other relevant information; and
6. Rules must be designed to achieve the objective in a cost-effective and timely way.

The legislature's rulemaking reforms included measures to facilitate public notice of and input regarding proposed new rules. Agencies must post proposed new rules on their websites, along with an explanation of the proposed rules and the reasons behind them, any fiscal notes or federal certifications for the proposed rules, and instructions on how and where to submit comments on the proposed rules.

Under the new rulemaking mandates, each agency must quantify the costs and benefits of a proposed regulation to the maximum extent possible. Where two or more agencies have overlapping policies and programs, the agencies are now expressly required by statute to coordinate their rule-making efforts to avoid unnecessary, unduly burdensome, or inconsistent regulations.

For any new rule that is designed to implement federal law, required for compliance with federal law, or on which the receipt of federal funds is conditioned, the agency must prepare a certification identifying the federal law and explaining why the proposed rule is required by the federal law. If the proposed rule goes beyond the requirements of federal law, this certification must explain why. The legislative changes include even stricter limitations on new environmental rules, which essentially prohibit environmental agencies from adopting regulations for the protection of the environment or natural resources that are more restrictive than any federal law or rule, unless certain specified conditions are met.

Finally, the legislature reemphasized existing North Carolina law that an agency may not enforce against a person any policy, guideline or interpretive statement that meets the definition of a rule unless it has been adopted as a rule. In other words, an agency cannot sidestep the rulemaking process by adopting a binding standard or requirement under the guise of an informal policy or interpretive statement.

### Annual Review of Existing Rules

In addition to changes governing future rules, the General Assembly established a Rules Modification and Improvement Program, which will be coordinated and overseen by OSBM. Under this program, each agency must critically review its existing rules annually to identify any rules that are unnecessary, unduly burdensome, or inconsistent with the new general rulemaking principles established for future rules. The OSBM will invite public comments on existing rules, assemble and evaluate public comments received, and forward for further review to the agency at issue any comments it deems to have merit. Each agency must review the public comments and report on whether any of the public's recommendations have merit or justify further action. Agencies must repeal any nonconforming rules identified in this review.

The General Assembly sent an unmistakable message that agencies are being reined in. Only time will tell what the actual practical and legal ramifications, costs and benefits, and efficiencies of this new rulemaking framework will be. Likewise, it remains to be seen how agencies and the OSBM will be able to carry out all of tThese rulemaking mandates effectively with fewer resources as a result of budget reductions. Meanwhile, hospitals and other state-regulated businesses and individuals in North Carolina have a new playbook to follow, which includes increased opportunities for commenting on existing and proposed rules and their economic impact and for understanding the agencies' reasoning behind both existing and proposed new rules.

## About Wilson Hayman, Editor of *Corridors*

Wilson's practice focuses on Health Law, Appellate Law, Civil Law, and Administrative Law. Wilson has represented public and private hospital systems as lead counsel in the acquisition and sale of hospitals, physician practices, and HMOs; represented health care providers in the formation and operation of provider-owned and -controlled managed care organizations, including IPAs, PHOs, MSOs, and HMOs; and represented hospitals and physicians in the drafting and negotiation of all types of physician services, recruitment, employment, and managed care contracts.

Wilson may be reached at 919.783.1140 or whayman@poynerspruill.com.

# Sixty Golden Days (to Pay Back the Feds)

***By Steve Shaber***

As a sequel to our article "T Minus Sixty Days and Counting" in the Winter 2010, issue of *Corridors*, this article discusses some practical procedures for hospitals and other providers to handle overpayments and repayments. In the world of medicine, the "golden hour" is that small window of opportunity within which the lives of cardiac, stroke or trauma patients can be saved. Similarly, providers who are overpaid by Medicare or Medicaid have their own "golden hour" for reporting and returning such payments. Fortunately, providers do not have just an hour to respond concerning overpayments but instead have a golden 60 days. But the idea is the same—immediate action is the key to survival.

The Patient Protection and Affordable Care Act (PPACA) has instituted a "60-day rule" that requires any person who has received a Medicare or Medicaid "overpayment" to which the person "is not entitled" to report such overpayment and return it within "60 days after the date on which the overpayment was identified." There is a separate rule for cost reports, which we do not address here.

By itself, this obligation to repay does not really change things. Certainly, the debt has to be repaid, but whether it is repaid now, or sooner, or later would not seem to matter very much. However, under PPACA, after the golden 60 days have passed, keeping the money becomes a federal false claim (a so-called "reverse false claim"), and civil money penalties and exclusions come into play. How severe are these penalties? The civil penalties can cost up to $11,000 per claim, and damages can be two or three times the amount of the entire overpayment. So 1,000 false claims totaling $1 million in overpayments (1,000 x $11,000) equals $11 million, plus 3 x $1 million = $3 million, equaling a total of $14 million in civil penalties and damages. Add in the provisions exclusion from the programs, and suddenly those golden 60 days become terribly important.

Unfortunately, it can be hard to tell when the 60 days begin to run. The law says they start when the overpayment is "identified," but it does not say how to spot that moment in time. Lawyers, consultants, and regulators disagree about what "identified" might mean. Consequently, providers have to make reasonable judgments and hope for the best.

In attempting to determine when your golden 60 days begin to run, ask yourself these four questions:

1. When did my organization first have good cause to suspect (genuine, sensible reasons to suspect) there may have been specific overpayments?
2. From the time my organization first had good cause to suspect such overpayments, did we work diligently to find out if we received overpayments and, if so, how much we were overpaid?
3. Now, am I reasonably sure there were such overpayments?
4. Now, am I reasonably sure about the amount of such overpayments?

If your organization works diligently on the problem from the time it first reasonably suspected something was amiss, then your 60-day reporting and repayment period should not start to run until you are reasonably certain there was an overpayment and reasonably certain of the amount. This means you still have another 60 days, calculate your actual overpayment, report it, and repay it.

On the other hand, if your organization had reasons to suspect an overpayment but failed to investigate them diligently, all you can do is assume you are already into your golden days and complete the investigation, calculate the overpayment, report it, and repay it as soon as possible.

A good thing about these four questions is that they can be restated as standard policies for your organization, such as the following:

1. Anyone who has reason to suspect the organization may have received reimbursement it should not have received must report the reasons for this suspicion to the compliance officer.
2. All reasonably suspected overpayments will be carefully investigated, beginning immediately upon their being reported to the compliance officer.
3. Once the investigators are reasonably certain an overpayment has occurred and are reasonably certain of the overpayment amount, the overpayment has been identified.
4. The amount of the overpayment shall be calculated, reported, and repaid not more than 60 days after the overpayment is identified.

If the entire overpayment cannot be fully calculated in that time, whatever part of the overpayment can be calculated should be reported and refunded, and the remainder of the overpayment should be calculated, reported, and repaid as quickly as possible thereafter. If your organization's standard procedures allow some leeway in identifying overpayments, as the suggested policies above do, it would be best not to take any extra time to act after the overpayments are identified.

Eventually the government will give us better guidance about the 60-day rule. For now, however, every provider needs to treat overpayments as emergencies by returning them within the golden 60 days in order to avoid severe penalties.

Steve Shaber may be reached at sshaber@poynerspruill.com or 919.783.2906.


# Encouraging Teamwork: CMS' Bundled Payments Initiative

## *By Kim Licata*

In August, the Centers for Medicare & Medicaid Services (CMS) announced another health care reform initiative aimed at incentivizing coordination of care and efficient health care delivery. The initiative for bundling payments for episodes of care is a mechanism for hospitals and other providers to align service delivery with CMS's triple aim of better care, better population and individual health, and lower costs. Taking advantage of this initiative will require teamwork and coordination among hospitals, physicians, and post-acute care providers, like many programs under P-PACA.

Bundling payments for health care services is not a new model for reimbursement. CMS currently pays for certain services through global payments, such as some surgeries, where providers must manage the costs of care for all services – pre-through post-procedure. Bundled payments have not been extensively used by CMS, in part because of industry push back. With the need for substantial market reform to maintain the financial viability of the U.S. health care system, P-PACA tests several models for attaining reimbursement reform by shifting the focus from quantity to quality of services. P-PACA's bundled payments, accountable care, and value-based purchasing programs are all designed to implement a fundamental change in health care delivery and drastically reduce health care costs.

The bundled payment initiative (BPI) is currently voluntary and by application only. In a teleconference to announce the BPI, CMS invited providers to apply to participate in the BPI to help test and develop the models of bundling payments so that both CMS and providers could collaborate on creating a fair payment mechanism for episodes of care, while better managing costs and coordinating care across providers. Three models proposed are based on retrospective payment bundling, while the fourth involves a single prospectively determined bundled payment to a hospital for all services furnished during an inpatient stay. The four models are defined by what is included in an episode of care:

**Inpatient Stay Only:** Model 1 defines the episode of care as all hospital services provided during an inpatient stay at a general acute care hospital. Only Part A fees are bundled; Part B services are unaffected. All diagnosis related groups (DRGs) may be subject to this model (unlike Models 2, 3, and 4 where the applicant proposes certain DRGs). CMS will make a discounted inpatient prospective payment system payment to participants based on the discount proposed by the applicant. Model 1 is based in part on the Medicare Hospital Gainsharing Demonstration Project.

**Inpatient Stay plus a defined period of Post-Acute Care:** Under Model 2, the applicant defines the episode of care to include all inpatient stay services, plus a fixed period of related post-acute care (from 30 to 90 days, also set by the applicant), including related readmissions and other defined services. Applicants propose the clinical conditions subject to the bundled payment and a target price. CMS makes the traditional fee-for-service (FFS) payments, which are retrospectively reconciled with the predetermined target price.

**Post-Acute Care Only:** Model 3's episode of care covers post-acute care services, related readmissions, and other defined services. Like Model 2, applicants propose the clinical conditions subject to the bundled payment and propose a target price. Payment is made on an FFS basis with a retrospective reconciliation.

**Prospective Inpatient Stay Only:** Model 4 covers all hospital and physician services (and related readmissions) during an inpatient hospital stay. Applicants propose the DRGs for which the applicant wants to receive a bundled payment and agree to a prospective payment rate. CMS pays the negotiated prospective payment and the applicant is responsible for distributing payment. Model 4 is based on the Medicare Acute Care Episode Demonstration Project.

Each model requires that the applicant propose a discount on payments made by CMS to the applicant (with minimum discounts set by CMS), and any additional savings achieved by the applicant may be distributed according to a previously developed gainsharing plan. Model 1 involves a discounted payment, while Models 2 and 3 involve a retrospective reconciliation of the FFS payment with the predetermined target price. In Model 4, the admitting hospital receives a single bundled payment of the predetermined amount from which it will distribute payment to the hospital and physicians. These differences permit CMS (and providers) to assess what works and what doesn't when bundling payments in different settings and for a variety of providers. Under each model, applicants will be required to meet certain quality measures, give notice to beneficiaries of services subject to a bundled payment, and ensure beneficiary choice, among other requirements.

Hospitals that have developed successful processes and methods for coordinating care, managing costs, and efficiently providing quality care can embrace the BPI as an opportunity to increase revenue through savings from the negotiated prices. Success will depend on developing a reasonable proposal, distribution plan, and culture of teamwork among the care delivery team. Keep in mind, the BPI applies only to the base payment from CMS and not to any additional payments, such as graduate medical education payments or disproportionate share payments. The BPI represents another step toward necessary and inevitable health care reform.

**What Can You Do?** Go to the CMS Innovation Center website, www.innovations.cms.gov, follow the links to BPI, and review the relevant guidance prepared by CMS. CMS envisions the BPI as a partnership between the agency and providers. As such, providers should participate in the BPI to have a role in setting current (and likely future) reimbursement methodologies. Applicants for Model 1 must submit a nonbinding letter of intent (LOI) by September 22, 2011, with a target start date of January 2012, while applicants for the other models must submit their nonbinding LOIs by November 4, 2011, for a program start date of March 2012. Applicants must complete an application, submit (and comply) with a data use agreement in certain cases, and propose other terms on the relationship, as requested by CMS.

Kim Licata may be reached at klicata@poynerspruill.com or 919.783.2949.

Poyner Spruill LLP

# HRcorner

## Employers: Make Sure Your Agreement with Electronic I-9 Providers Is Adequate for Peace of Mind

*by Jennifer Parser*

As most employers know, Immigration and Customs Enforcement (ICE) is increasing its efforts to stop illegal employment. Short-staffed and lacking resources to perform a lengthy stakeout and raid at an employer's premises, ICE is using a softer, but no less chilling, method. A simple letter from ICE, called a Notice of Inspection, notifies an employer that it has 72 hours to produce its I-9s for ICE's inspection. Because fines are substantial and ICE can now ship thousands of I-9s to its new inspection center in Virginia (established to handle large numbers of I-9s), employers are frequently turning to external electronic providers for I-9 storage (usually linked with E-Verify) as a cost-effective and secure alternative to paper I-9s. This may be an excellent solution—particularly in view of pending federal legislation—but certain aspects bear consideration when choosing an electronic I-9 provider, as LexisNexis discovered.

In June 2011, LexisNexis filed a complaint alleging breach of contract against USVerify, an I-9 and E-Verify service provider, under a five-year reseller agreement, wherein LexisNexis would resell USVerify services to its customers. USVerify agreed to provide LexisNexis with services that would permit an end user to complete an I-9 online, with USVerify providing storage, maintenance, and tracking services. The end user could also conduct a right-to-work verification through E-Verify, and USVerify was to maintain the end user's historical E-Verify data.

When LexisNexis notified USVerify of its intent not to renew its contract upon expiration and requested that its I-9 information be returned in a format suitable for another I-9 service provider to access it, USVerify refused, maintaining that it should be compensated for this additional work and that it would contact LexisNexis customers to inform them of the need to make arrangements for replacement services. LexisNexis filed an injunction requiring the service provider to return all customer information, produce all I-9 information in a usable and readily accessible format, maintain all I-9 information during the transition period, provide the government (if requested) with ready access to the same in the event of an ICE inspection, and cease and desist from using any information about LexisNexis customers.

LexisNexis was granted a preliminary injunction, and USVerify was ordered to return all information that LexisNexis customers needed to comply with I-9 retention, maintenance and E-Verify. Despite USVerify maintaining that the I-9s, audit trails, and results were produced by proprietary software and were therefore its intellectual property and not the property of LexisNexis or its customers to access, the court disagreed. It decided that all information had to be turned over by USVerify, regardless of whether the request came from LexisNexis, its customers, or the Department of Homeland Security. The time and expense for LexisNexis to reach that point would probably have been unnecessary had its agreement with USVerify had been clearer. Optimally, the agreement between an electronic I-9 provider and an employer should not only identify who owns the information but also spell out what that data is exactly. The I-9s are much more than PDF documents and must include information such as electronic signatures and audit trails. Moreover, to avoid the situation where the electronic provider demands a fee for a customer to retrieve its data, the agreement should specify that all data be returned promptly *gratis* in a readily accessible and usable format.

The Legal Workforce Act (H.R. 2164), sponsored by House Judiciary Committee Chairman Lamar Smith, is now before the Senate. When this bill becomes law, it will be mandatory for all employers nationwide to run all new hires through E-Verify by a gradual phasing in based upon its number of employees. Fines would increase between twofold and tenfold, with a possible wavier for violators who can establish they acted in good faith. With this bill pending and various states like North Carolina requiring E-Verify's use, contracting with an electronic I-9 provider that combines I-9 storage with E-Verify capability is not a bad idea. However, the agreement must protect the employer by adequately defining subject matter, ownership, and rights and obligations upon termination, including the prompt, free return of data in an accessible and usable format.

Jennifer Parser practices in the areas of immigration, employment, and international law. In her practice, she assists clients with a variety of immigration and employment issues. Jennifer may be reached at jparser@poynerspruill.com or (919) 783-2955.