OUTLOOK ON HEALTH REFORM: THE CLOCK IS TICKING

As Democratic leaders continue to negotiate and reconcile the remaining pieces of a compromise healthcare reform bill, the January 19 election of Republican Scott Brown for the Senate seat held by the late Sen. Ted Kennedy (D-Mass.) has thrown the Democrat's strategy for passing healthcare reform into disarray.

Reform deliberations dominated the Senate during the month of December culminating with the passage of the Patient Protection and Affordable Care Act (H.R. 3590) on a party line vote (60-39) early Christmas Eve. Since that time, Democratic leaders in both chambers have worked with the administration to reconcile key differences between the House and Senate bills. Chief among those requiring resolution and agreement before a compromise measure can be achieved are:

- Federal or state administered exchanges, with or without a public option
- Tax credits and subsidies for the purchase of health insurance
- Penalties and exemptions for the uninsured
- Taxes on expensive "Cadillac" insurance plans
- Repeal of the insurance industry's antitrust exemption
- Abortion coverage
- An independent payment board to reduce Medicare spending
- Closing the Medicare prescription drug "donut hole" gap
- Reductions in Medicare and Medicaid disproportionate share payments
- Expanded eligibility for Medicaid
- The survival of the Children’s Health Insurance Program

So what are the possible scenarios for passage? The House could pass the Senate bill without any changes and send it directly to the President for his signature, with or without a "cleanup" bill to follow later; the House and Senate could finish negotiating a reconciled bill and pass it before the Commonwealth of Massachusetts certifies the Brown election and he is seated in the Senate (approximately 10-12 days post-election); lawmakers could resort to a number of "parliamentary gymnastics," including a procedural option known as reconciliation to push through a negotiated bill or a follow-on "clean-up" bill; Democrats could try to secure a Republican vote (i.e., Olympia Snowe (R-Maine)) in the Senate or pass a scaled-back bipartisan bill or begin the process anew.

Greater clarity regarding which track healthcare reform likely will take should emerge in the coming days and certainly by the time President Obama delivers his State of the Union address on January 27, 2010. In the meantime, providers should continue to factor the myriad of proposed business, coverage and delivery system reforms present in both the Senate and House bills in their strategic planning.
HEALTH REFORM’S IMPACT ON PROVIDERS AS EMPLOYERS: KEY ISSUES TO CONSIDER

While the pending healthcare reform legislation will affect how healthcare providers furnish goods and services within the larger healthcare delivery system, providers also should consider how the reform legislation will affect them as employers and as the recipient of other workers’ personal services. Because the reform legislation is intended to rebalance how the costs of the healthcare delivery system are borne by private industry, government and the general public, it fundamentally will change how all businesses, including healthcare providers, provide and pay for the healthcare coverage their employees and other healthcare workers receive.

Healthcare providers will need to consider and address at least the following six key issues when deciding what healthcare coverage to provide or make available to their employees and how to handle other workers who provide non-employee services to them:

- Individuals will have greater direct access to individual health insurance coverage by purchasing group coverage commercially and will have an obligation to either buy the coverage directly or obtain it indirectly through an employer. Changes in the accessibility of coverage likely are to change the traditional imperative that a healthcare provider must provide coverage, or provide certain types of coverage, to its employees through an employer-sponsored or union co-sponsored plan.
- Providers that currently offer coverage to their employees through an employer-sponsored plan may not have to make significant changes to their plans or improve the coverage presently being provided. However, all plans will have to be reviewed to meet minimum standards and conform to the new rules expected to emerge. A so-called “grandfather” rule, to protect existing plans from having to make major changes, will at least provide transitional relief.
- Providers that use an employer-sponsored plan to provide coverage to employees will have to comply with several new administrative rules and compliance obligations, including, in some cases, automatic enrollment rules and new reporting requirements.
- The impact on specific providers will vary, due to the uncertain effects of such a substantial redistribution of the benefits and burdens of the healthcare delivery system. Factors affecting the impact will include the number of full-time employees in the employer’s workforce; how coverage is provided (e.g., by purchasing commercial coverage, through self-insurance, etc.); whether the covered population is located in high-cost or low-cost states; whether the workforce can be relocated or realigned or can be rearranged; whether the plan-covered population is heavily weighted towards younger employees or older employees, or includes substantial numbers of retired and other former employees; and similar considerations.
- Healthcare providers that rely on a composite workforce to provide their services, including part-time employees, independent contractors, "dependent" contractors and "shared" and leased employees, likely are to face special challenges. The current reform legislation sharply distinguishes between large employers and small employers in terms of the obligations each faces, and generally leaves seasonal and part-time employees and independent contractors with the burden to purchase coverage for themselves. The new economic burdens imposed by the reform legislation...
will create new incentives for individuals to challenge traditional work classifications or attempt to modify them (possibly by seeking to organize and bargain collectively).

- The general marketplace reforms contained in the legislation are set to take effect for plan years beginning six months after enactment (generally starting in 2011). However, most substantive employer provisions begin to take effect in 2014, and some provisions are not scheduled to take effect prior to 2018. Delayed effective dates, and the need for several of the provisions to be interpreted by regulatory agencies, provide the opportunity to analyze and plan for the upcoming changes for at least the next several years. In addition, the reform legislation makes employers responsible for full-time employees only, which is likely to prompt many employers to review the composition of their respective workforces.

No matter what the final reform legislation looks like, healthcare providers are well served by taking into account not only the direct impact reform will have on their business model, but also how reform will affect what health benefit coverage they provide to their employees and how they obtain services from workers for whom they would not have any direct obligations.

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COBRA SUBSIDIES AND PHYSICIAN PAY CUTS: THE FEBRUARY DEADLINES ARE FAST APPROACHING

Tucked deep within the U.S. Department of Defense Appropriations Act (H.R. 3326, Pub. L. 111-118), signed into law by the President on December 19, 2009 (hereinafter, the DOD Appropriations Act), are two provisions of note for the healthcare industry with important deadlines:

- When President Obama signed the American Recovery and Reinvestment Act (ARRA) on February 17, 2009, he enacted legislation providing a 65 percent COBRA premium subsidy for up to nine months to eligible employees involuntarily terminated between September 1, 2008, and December 31, 2009. The DOD Appropriations Act extends both the maximum COBRA premium subsidy period from 9 to 15 months and the eligibility deadline from December 31, 2009, to February 28, 2010.
- On November 25, 2009, the Centers for Medicare & Medicaid Services (CMS) published its final rule establishing the Medicare Part B physician fee schedule for CY 2010 which reflected a 21.2 percent payment cut as mandated by the sustainable growth rate adopted by Congress in 1997. As with prior years, Congress intervened to override the proposed reduction -- this time via the DOD Appropriations Act -- which freezes Medicare payment for physicians at current levels through February 2010.

While the temporary extensions provided a modicum of breathing room for lawmakers deliberating healthcare reform, the February deadlines are fast approaching. Although Congress has promised to permanently fix the Medicare physician fee schedule this year, the outlook for early action continues to be cloudy as prospects for passing healthcare reform remain in question.

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MORE TO FOLLOW? CONNECTICUT AG BRINGS FIRST HIPAA VIOLATION CASE

Last week, Connecticut Attorney General Richard Blumenthal sued Health Net of Connecticut (Health Net), which is part of Health Net, Inc., a multi-state managed care company, for violations of the Health Insurance Portability and Accountability Act (HIPAA). Health Net was accused of failing to secure private patient medical records and financial information involving 446,000 Connecticut enrollees and to promptly notify consumers endangered by the security breach. Pursuant to a section of the economic stimulus bill, state attorneys general are able to bring actions to enforce HIPAA, and it is believed that this is the first such action.

The lawsuit stems from the disappearance in 2009 of a portable computer disk drive from Health Net's offices. The drive contained protected health information, social security numbers and bank account numbers for 1.5 million current and former members, including 446,000 in Connecticut. The drive contained millions of documents, including insurance claim forms, membership forms, appeals and grievances, correspondence and medical records. The information was not encrypted and could be viewed using commonly available software.
The complaint alleges that Health Net violated HIPAA because it did not ensure the confidentiality and integrity of Protected Health Information (PHI); supervise and train its workforce on policies and procedures concerning the appropriate maintenance, use and disclosure of PHI; and promptly notify Connecticut authorities and residents of the breach. According to the complaint, Health Net discovered the breach in May 2009 but did not notify affected consumers until nearly six months later.

It is expected that other attorneys general will utilize the HIPAA enforcement powers granted under the Health Information Technology for Economic and Clinical Health (HITECH) Act. This case underlines the importance of all entities covered by HIPAA not only to take actions that ensure encryption and other safeguards are used, but also to maintain robust data breach policies and procedures and provide training on how to respond in the event of a data breach.

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CERTIFIED ELECTRONIC HEALTH RECORDS: THE MEANING OF MEANINGFUL USE

On the cusp of the new year, CMS and the Office of the National Coordinator for Health Information Technology (ONC) released copies of closely related rules to implement provisions of the HITECH Act which provides for incentive payments for the adoption and meaningful use of certified electronic health record (EHR) technology. These proposed and interim final rules delineate the preliminary standards, specifications and certification criteria for EHR technology and the much-awaited definition of "meaningful use."

Meaningful Use and Staged Set-Up

Meaningful Use Defined

In general, an eligible provider or hospital must be a meaningful user of certified EHR technology in order to receive Medicare and Medicaid incentive payments. To qualify as a meaningful EHR user, three requirements must be satisfied:

- The provider or hospital must use certified EHR technology in a meaningful manner (e.g., electronic prescribing);
- The provider or hospital must use certified EHR technology to improve the overall quality of care; and
- The provider or hospital must submit information on clinical quality measures to CMS.

Phased Approach

CMS proposes to use a three-stage phased approach to introduce the meaningful use criteria. The longer an eligible provider or hospital delays implementing certified EHR technology, the more rapidly it will need to progress from Stage 1 to Stage 3 to receive the full incentive payments. Currently, the proposed rule only provides the goals of Stage 1 which focus on:

- Electronically capturing health information in a coded format;
- Using that information to track key clinical conditions and communicate for coordination of care purposes;
- Implementing clinical decision support tools to facilitate disease and medication management; and
- Reporting clinical quality measures and public health information to government agencies.

CMS will update the criteria periodically, and estimates that the Stage 2 and 3 criteria will be proposed by the end of 2011 and 2013, respectively.

Incentive Programs

The Medicaid and Medicare incentive programs for the adoption of certified EHR technology are separate programs, but share a common definition for meaningful use. Providers should note there are strategic differences between the two programs concerning eligibility and payment structure. Eligible Professionals (EPs) who are eligible for both the Medicare and Medicaid program may only participate in one program. Eligible hospitals, on the other hand, can qualify to receive payments from both Medicare and Medicaid EHR incentive programs.

Under the Medicare program, an EP is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry or a chiropractor who is legally authorized to practice under state law. CMS has proposed that hospital-based EPs – those who furnish 90 percent or more of their allowed services in hospital inpatient, outpatient and emergency department settings – will not be eligible for incentive payments. Qualifying
EPs can receive incentive payments beginning as early as 2011 and for up to five years. Generally, the maximum total incentive payment an EP can receive under the Medicare program is $44,000.

Eligible hospitals under the Medicare program include "subsection (d)" hospitals located within the 50 states or the District of Columbia and which are paid under the hospital inpatient prospective payment system. Eligible hospitals that meet the requirements for demonstrating meaningful use can receive incentive payments for up to four fiscal years for fiscal year beginning in October 2010. Hospital incentive payments are based upon a complex calculation that accounts for discharges, inpatient bed days and charity care.

Under the Medicaid program, EPs include a slightly different cast of eligible providers: physicians, dentists, nurse practitioners, certified nurse midwives and physician assistants practicing predominantly in a Federally Qualified Health Center or Rural Health Clinic (FQHC/RHC) that is directed by a physician assistant. Similar to the Medicare program, EPs are not eligible if 90 percent or more of their services are performed in a hospital setting. EPs must meet patient volume thresholds (e.g., 30 percent Medicaid), and can receive up to $63,750 over the six-year period, with maximum payment achieved by early adoption and meaningful use of qualifying EHR. Eligible hospitals include acute care hospitals and children’s hospitals. The Medicaid incentive payment for hospitals is based on a statutory formula focusing on a hospital’s Medicaid share.

"Certified EHR Technology": Standards, Implementation Specifications & Certification Criteria

Separately, in an Interim Final Rule published on December 30, 2009, the ONC released an initial set of standards, implementation specifications and certification criteria as "the first step in an incremental approach to adopting . . . [the] criteria to enhance the interoperability, functionality, utility, and security of health information technology." The criteria set forth in the Interim Final Rule are those necessary for an eligible provider or hospital to achieve Stage 1 of the "meaningful use" of "Certified EHR Technology" under the HITECH Act.

The Interim Final Rule follows similar terminology to that used in the HIPAA Privacy and Security Rules, in that it establishes "standards" and "implementation specifications" for four areas of EHR development and use: (1) vocabulary systems, (2) content exchange, (3) transport of information and (4) privacy and security of EHR technology. Although the rule identifies standards and criteria that support HIPAA security compliance, the rule focuses strictly on the capabilities of certified EHR technology and does not alleviate the need for a HIPAA security risk assessment and appropriate implementation of, or modifications to, a provider’s compliance program and processes. The Secretary of the U. S. Department of Health and Human Services (HHS) states, the rule "does not change existing HIPAA Privacy or Security Rule requirements, guarantee compliance with those requirements, or absolve an EP or eligible hospital, or other healthcare provider who adopts Certified EHR Technology from having to comply with any applicable provision of the HIPAA Privacy or Security Rules."

The Interim Final Rule gives providers the option to satisfy the criteria for certified EHR technology through two methods. First, a provider may implement a “Complete EHR” system, which has been developed to meet all applicable certification criteria established by HHS. The second method is to assemble a combination of "EHR Modules" which are individually certified as meeting the specific functional criteria it is designed to address. However, assembling EHR Modules must be done in a way that ensures that the EHR Modules each are certified as meeting all of the applicable certification criteria, and the grouping of EHR Modules includes all of the capabilities required by the EHR certification criteria.

The public may comment on the Interim Final Rule through March 15, 2010. Providers should be aware that these EHR standards and implementation criteria are only the beginning of a lengthy process. HHS states that “the requirements for meaningful use will become more demanding over time, and consequently that certified EHR technology will need to include greater capabilities, as well as the ability to exchange electronic health information in a variety of circumstances with many different types of health information technology." Additional HHS rulemaking is expected shortly after this rule, with respect to the criteria for the HIT Certification Program, which will issue standards for the processes that a certification body will need to follow to become authorized by ONC to certify EHR technology, including standards for the EHR technology certification process itself.

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NONPROFIT ORGANIZATIONS: FIDUCIARY DUTIES OF DIRECTORS AND OFFICERS IN MANAGING INVESTMENTS

Houston partner, Robert M. Wolin authored a Member Briefing on “Fiduciary Duties of Nonprofit Directors and Officers in Managing Investments” for the Business Law and Governance Practice Group of the American Health Lawyers Association. The briefing, which provides an analysis of directors' and officers' fiduciary duties in overseeing the management of nonprofit organizations’ investment portfolios, outlines important practical strategies for reducing potential exposure.

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IME RESIDENT RESEARCH TIME: ANOTHER DISTRICT COURT WEIGHS IN

On December 30, 2009, the District Court for the Eastern District of Michigan joined numerous district courts in ruling that resident research time must be included in a hospital’s full-time equivalent (FTE) resident count for purposes of indirect medical education (IME) reimbursement during time periods prior to 2001. See Henry Ford Health System, d/b/a/ Henry Ford Hospital v. Sebelius, 2009 WL 5217661 (E.D. Mich. 2009).

The Eastern District of Michigan joined the Southern District of Ohio, the District of Arizona, the Northern District of Illinois and the District of Rhode Island in finding that the IME regulation in place prior to 2001, which called for residents to be included in a provider’s IME FTE count if they are assigned to "the portion of the hospital subject to the prospective payment system," allows the inclusion of residents engaged in educational research.

The Henry Ford court held that the regulation’s reference to "the portion of the hospital subject to the prospective payment system" is a geographic (as opposed to functional) question, and that such a conclusion is mandated by a reading of the regulation in its entirety, as well as the agency’s intent at the time of rulemaking.

The Henry Ford decision runs counter to a recent First Circuit Court of Appeals decision in which the First Circuit held that the regulation was ambiguous, and therefore, the Secretary’s refusal to include resident research time in the IME count was permissible. See Rhode Island Hospital v. Leavitt, 548 F.3d 29 (1st Cir. 2009). Thus far, Rhode Island Hospital is the only circuit court decision on the IME research time issue; the Arizona and Ohio cases were not appealed, and it remains to be seen whether Henry Ford will be appealed and whether a circuit split on the issue may result.

In addition to the IME research time issue, the Henry Ford case involved two additional questions: whether the Secretary improperly excluded two of the hospital’s residency programs from inclusion in the 1996 cap exclusion for counting FTE residents, and whether the Secretary improperly denied a remand to the intermediary for consideration of the hospital’s claims for reasonable cost reimbursement under Medicare Part B.

With respect to the former question, the court held that although the two residency programs at issue trained residents prior to the FTE cap cutoff date, the programs did not gain accreditation until later, thus allowing the programs to meet the definition of "new programs" and meet the regulatory exception for counting residents in new medical residency training programs established on or after January 1, 1995, and before August 5, 1997. 42 CFR § 413.86(g)(1998).

Concerning the latter issue, the court held that the provider did not provide sufficient evidence to support its alternative argument in support of obtaining Medicare Part B reimbursement for the costs of unapproved programs at the administrative level, and therefore, the Secretary’s refusal to remand the issue to the intermediary to review the evidence was proper.

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OHIO HEALTHCARE TEAM MEMBERS NAMED TO SUPER LAWYERS

Ohio Healthcare Team members Christopher J. Swift and Richard W. Siehl have been named to the 2010 "Ohio Super Lawyers" list and are included in Ohio Super Lawyers magazine and special sections of the January 2010 editions of Cincinnati Magazine and Columbus Monthly magazine. "Super Lawyers" is a comprehensive and diverse listing of outstanding attorneys representing a wide range of practice areas, firm sizes and geographic locations. The 2010 "Super Lawyers" lists are based on surveys of thousands of lawyers and only the top five percent of lawyers from nearly 70 practice areas are named to the list. Mr. Swift is a partner in the Cleveland office. Mr. Siehl, also a partner, divides his time between the firm’s Columbus and Orlando offices.
Houston partner, Robert M. Wolin was recently awarded board certification in health law by the Texas Board of Legal Specialization (TBLS). Authorized by the Supreme Court of Texas, the TBLS awards certificates of special competence to attorneys who demonstrate experience, training and knowledge in one of 20 specific areas of the law. To become board certified in health law, attorneys in Texas must devote a significant percentage of their practice to operations, regulatory and transactional legal issues, successfully pass a six-hour written examination and be evaluated by their peers.