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Sebelius Faces Senate Confirmation Hearings but Confirmation Vote Is Weeks Away

Senate Health, Education, Labor, and Pensions Committee Hearing

On March 31, 2009, the Senate Committee on Health, Education, Labor, and Pensions (HELP) held a confirmation hearing on President Obama's nomination of Kansas Governor Kathleen Sebelius for Secretary of Health and Human Services (HHS). Governor Sebelius faced a relatively friendly group of senators, but the few points of contention centered on her position on health care reform rather than her qualifications for HHS Secretary.

At the outset, Governor Sebelius made clear that, if confirmed, health care reform would be her top priority. Committee ranking member Michael Enzi (R-WY), who is generally in support of health care reform legislation, expressed hope that Governor Sebelius would discourage lawmakers from using budget reconciliation, which would enable the Senate to pass a health care bill with just 51 votes rather than the 60 normally required in the Senate, to move health reforms through Congress. Governor Sebelius asserted that although President Obama would prefer that health reform be bipartisan, he is not ready to tie his own hands by taking reconciliation off the table.

Faced with direct questions from Senator John McCain (R-AZ), Governor Sebelius refused to support eliminating the employer-sponsored health insurance tax exclusion in exchange for a tax credit. Governor Sebelius did express strong support for a public health plan that would compete side-by-side with private options in an insurance exchange system.

Echoing the concerns of lawmakers and the Obama Administration, Governor Sebelius noted that the Medicare system is fraught with waste, fraud and abuse. She agreed with Senator Tom Coburn (R-OK) when he suggested a need for "preemptive strikes" to let the health care industry know that "there's a new sheriff in town." Governor Sebelius also pledged to work across party lines, address the shortage of physicians in rural areas, and ensure that the Centers for Medicare & Medicaid Services follows the American Recovery and Reinvestment Act's mandate that agency officials not consider costs when conducting comparative effectiveness research.

Senate Finance Committee Hearing

On April 2, 2009, the official confirmation hearing was held before the Senate Finance Committee, which has the power to recommend Governor Sebelius's confirmation to the Senate. Like the HELP Committee hearing, the Finance Committee hearing featured bipartisan goodwill for the nominee and a sense of urgency that an overhaul of the health care system is essential this year.

Following on the heels of the Senate HELP Committee hearing, the Finance Committee hearing was almost devoid of surprises. However, Governor Sebelius did break some new ground in her comments by stating that she thinks health care reform should fill the coverage gap in the Medicare prescription drug program known as the "doughnut hole." Democrats have shied away from talk of filling the gap because of the billions of dollars in expense involved. In addition, Governor Sebelius noted that she would welcome legislation giving the HHS Secretary the authority to negotiate the price of prescription drugs covered by the Medicare program.

Although Senator Baucus (D-MT), Chairman of the Senate Finance Committee, predicted a quick confirmation of Governor Sebelius, Republicans blocked confirmation claiming that the Senate should have a chance to debate the nomination. Therefore, the Finance Committee vote will be delayed until mid-April when lawmakers return from their two-week Easter recess.

CMS Releases Final 2010 Call Letter for MA Organizations and Part D Sponsors

The Centers for Medicare & Medicaid Services (CMS) has issued the final 2010 Call Letter for the Medicare Advantage (MA) and Medicare Part D Programs. The Call Letter provides guidance to help MA organizations and Part D plan sponsors prepare their bids for the upcoming plan year. CMS released the original draft Call Letter on January 8, 2009, withdrew it on January 22, 2009, and then reissued it on February 23, 2009 for public comment. CMS received about 190 comments in response to the draft Call Letter issued on February 23. In general, CMS in its final Call Letter does not make any new or sweeping changes from its draft.

Bids Due June 1st

Bids for the 2010 plan year are due on June 1. As this is the fourth year of the Medicare Advantage and Part D Programs, CMS expects plan corrections to be minimal. MA organizations' and Part D plans' request for plan corrections "indicate … the presence of inaccuracies and/or the incompleteness of a bid and call … into question an organization's ability to submit correct bids and the validity of the final actuarial certification." MA organizations that request a plan correction will receive a corrective action warning; Part D plan sponsors that request a plan correction will be out of compliance with the Part D Program's bid submission and certification requirements.

Renewed Focus on Program Oversight

This Call Letter is noteworthy as it is the first major instruction issued to MA organizations and Part D plans under the new administration, and it reflects a renewed focus on plan oversight for the 2010 plan year. For example, CMS indicates that its audit strategy for 2010 will focus on "more targeted, data-driven and risk-based audits." In addition, CMS intends to evaluate the effectiveness of the compliance programs of MA organizations and Part D plan sponsors, including the requirement for effective internal monitoring and auditing.

Data Validation Audits

The Call Letter also addresses CMS' concerns about the validity of the data it receives as part of the Part C and Part D reporting requirements. CMS plans to work with a contractor to develop data validation audit specifications for a limited number of reporting elements for 2010, including MA and Part D grievances, MA agent compensation structure, and Part D drug benefit analyses. These specifications will measure the data's reliability, validity, completeness, and comparability. CMS will develop data validation audit specifications for additional reporting elements in the future.

In the meantime, CMS strongly encourages MA organizations and Part D plans to engage outside contractors to audit the Part C and Part D data reported to CMS for accuracy. Further, CMS will ask a sample of Part C organizations and Part D plan sponsors to participate in a pilot study implementing the data validation specifications for certain elements in 2009.

Future Rulemaking

CMS suggests that it is considering notice and comment rulemaking procedures that would, among other things:

- limit the number of plan benefit designs MA organizations may offer in a given service area;
- impose an out-of-pocket threshold maximum amount for MA plans;
- prohibit private fee-for-service plans from using "prior notification" to reduce the standard plan cost sharing; and
- ensure that Part D plans do not use specialty tiers to discourage enrollment by certain classes of beneficiaries.

California Federal Court Retains Injunction Protecting Pricing Data in Laboratory Competitive Bidding Suit

A case pending before the U.S. District Court for the Southern District of California could determine whether HHS can use or disclose highly competitive pricing data submitted by clinical laboratories as part of the now-defunct Medicare demonstration project on competitive bidding for clinical diagnostic testing. On March 25, 2009, the court refused a motion by HHS to dissolve a preliminary injunction granted in April 2008 that blocked the demonstration project, despite the fact that Congress repealed the underlying statutory authority for the demonstration project in July 2008. The case, filed by Sharp Healthcare, Internist Laboratory, and Scripps Health, is *Sharp Healthcare v. Leavitt,* No. 08-CV-0170, slip op. (S.D. Cal. March 25, 2009). Under the court's order, the laboratories have until April 27, 2009 to file an amended complaint adding additional facts supporting their position to permanently bar HHS from using or disclosing competitive pricing data submitted as part of the competitive bid applications.

The laboratories filed suit in January 2008 to enjoin HHS from implementing the demonstration project, claiming that HHS failed to comply with the federal Administrative Procedure Act. The laboratories alleged that the demonstration project could cause irreparable harm if they did not win the bidding and result in adverse consequences for the thousands of patients they serve in the San Diego area. The court granted the preliminary injunction on April 8, 2008, well after the February 15, 2008 deadline for submitting bid applications containing pricing data and other competitive information for 303 laboratory tests. The April 2008 preliminary injunction, in relevant part, prohibited HHS from further disclosing any information included in the laboratories' bid applications. Congress repealed the statutory authority for the demonstration project on July 15, 2008 as part of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. No. 110-275, § 145).

Although the congressional repeal of the demonstration project rendered the majority of the case moot, in its March 25, 2009 decision, the court agreed with the laboratories' argument that HHS' retention of the bidding information meant that a controversy might still exist between the parties. The laboratories argued that HHS could use the bid prices contained in the laboratories' demonstration project applications to set Medicare reimbursement rates for laboratory services, and thus "achieve the goals of the demonstration project without going through with the actual project." The court acknowledged the possible merits of HHS's argument that the government is already prohibited from disclosing the data under the Trade Secrets Act, and that Medicare law requires the Secretary to cite the basis for any proposed Medicare rate changes. Nevertheless, the court held that the confidential and proprietary nature of the laboratories' data warranted preemptive relief.

In countering HHS's argument that the laboratories could not maintain the "likelihood of success" element of the preliminary injunction test, the court noted that, "in situations where the possible harm to plaintiffs is very great, less probability of success needs to be shown." If the laboratories fail to amend their complaint by the April 27th deadline to add a claim related to

HHS's "wrongful and unauthorized retention of the bid information," the court stated it would then "dismiss the action with prejudice, dissolve the preliminary injunction, and vacate the prior orders."

Institutional Review Board System Vulnerable to Unethical Manipulation, Reports GAO

On Thursday, March 26, the Government Accountability Office (GAO) testified before the House of Representatives regarding an undercover investigation into the Institutional Review Board (IRB) system. The testimony was before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce. According to the GAO, its investigation shows that the IRB system is vulnerable to unethical manipulation, which ultimately creates risks for human research subjects.

IRBs are multi-disciplinary committees that review and monitor human subject research with the intended purpose of protecting the rights and welfare of research participants. The GAO's investigation was aimed at independent IRBs, or IRBs that are not affiliated with academic medical centers, and raised questions about the sufficiency of the diligence review conducted by these organizations.

In order to investigate the IRB establishment and review process, the GAO created a fictitious research study to test a fictitious medical device on human subjects. The fake device had features of a "significant risk" medical device based on FDA guidance. The GAO's submission was accompanied by falsified investigator CVs, counterfeit medical licenses, and other falsified documentation.

While two IRBs rejected the GAO's protocol citing safety concerns, the GAO was able to obtain approval from one independent IRB. The IRB that approved the fictitious study reported that that the GAO's bogus device was "probably very safe."

Another aspect of the GAO's investigation involved creating a fictitious independent IRB. The GAO created a website and advertised the fictitious IRB's services in newspapers and on the internet, emphasizing the speed of its review process. The fictitious IRB had no medical expertise whatsoever, but it received inquiries from five actual companies interested in its services. Another real company submitted materials seeking the fake IRB's approval for a new test site for an ongoing trial involving invasive surgery.

According to Representative Bart Stupak (D-MI), Chair of the Subcommittee on Oversight and Investigations, the GAO's findings raise serious questions not only about the specific entities involved in the investigation, but about the entire system for approving experimental testing on human beings.

Approval Pathways for Biosimilars Being Considered by Congress

Biotech drugs may soon face generic competition. On March 26, 2009, Senator Charles Schumer (D-NY), together with six other co-sponsors, introduced a bipartisan bill that would create a pathway for approval of biosimilars, which are generic drugs made from living cells rather than from chemical syntheses. At present, biotech drugs (also called biologics or biopharmaceuticals) do not face generic competition because the FDA has no process to approve copies of biotech drugs. Chemical drugs, on the other hand, have been subject to generic competition since 1984, when the Hatch-Waxman Act created an FDA approval pathway for them. Because biotech drugs are extremely costly, and some projections show that these drugs might constitute 50% of all drugs approved in 2010, the push for an approval pathway for lower-cost equivalents is mounting in Congress.

Senator Schumer's bill would give the FDA authority to determine whether or not a generic biotech drug must undergo more extensive testing. One of the more controversial provisions in Senator Schumer's bill provides for a market exclusivity period for the innovator company of only five years from the time the brand-name drug was approved, plus an additional three years for modifications.

Senator Schumer's legislation is the third biosimilar bill introduced in March 2009 alone. The key differences between the bills involve the length of time that the innovating company can maintain exclusivity, during which time competitors cannot make generic equivalents. Representative Henry Waxman (D-CA), together with Representatives Frank Pallone (D-NJ), Nathan Deal (R-GA), and Jo Ann Emerson (R-MO), introduced a biosimilar bill in the House just a few weeks earlier, proposing a five-year initial exclusivity period. The competing bill in the House, introduced by Representatives Anna Eshoo (D-CA), Jay Inslee (D-WA) and Joe Barton (R-TX) on March 17, is more friendly to the innovator companies, allowing for a 12-year initial exclusivity period. Senator Edward Kennedy (D-MA) has also indicated his intention to reintroduce his biosimilar bill, which would provide for a 12-year exclusivity period.

Not surprisingly, the Generic Pharmaceutical Association backs the bills with the shorter exclusivity period, while the Biotechnology Industry Organization (BIO) backs Representative Eshoo's bill, though BIO advocates a 14-year exclusivity period. The exclusivity period for innovator biotech drugs in the European biosimilar approval process is 11 years.

Despite varying approaches, sponsors for each bill cite to the need to create an expedited approval pathway for biosimilars that results in lower cost drugs, while maintaining sufficient safeguards to ensure patient safety.

OIG Looks at Concurrent Employment and Real Estate Contracts

On April 2, 2009, the HHS Office of Inspector General (OIG) issued an advisory opinion (Advisory Opinion No. 09-02) regarding an employment contract with a mental health practitioner ("Practitioner") entered into concurrently with a contract for the employer to purchase real estate from the Practitioner. While the OIG concluded that the employment arrangement meets the safe harbor for employees under the Anti-kickback Statute, it expressed no opinion as to whether the purchase of the real estate implicates the fraud and abuse laws.

The Requestor is a corporation which provides mental health services. Prior to becoming employed by the Requester, the Practitioner operated her own mental health practice in a building that she owned, but then approached the Requestor's CEO with a proposal for the Requestor to purchase the building and operate a mental health clinic there. The Requestor agreed to purchase the building on the condition that the Practitioner would become the clinic director and a counselor. The parties thereafter entered into an employment agreement, which was expressly contingent upon the Requestor purchasing the Practitioner's building. The employment agreement provided that compensation to the Practitioner would be based on professional and administrative services personally performed by the Practitioner, as well as total revenues of the clinic. According to the Requestor, the Practitioner is a bona fide employee within the meaning of the Internal Revenue Code, and the purchase price for the building was "market value" and did not include payment for referrals.

In determining whether the employment arrangement constitutes grounds for sanctions under the Anti-kickback Statute, the OIG noted that the Statute excepts from its reach "any amounts paid by an employer to an employee, who has a bona fide relationship with the employer, for employment in the furnishing of any item or service for which payment may be made" under a federal health care program.[1] Relying on the Requestor's certifications that the Practitioner is, in fact, a bona fide employee and that the compensation she receives is based on the professional and administrative services she performs, the OIG concluded that the Practitioner's employment satisfies the employee safe harbor requirements.

The OIG did not, however, express an opinion as to whether the purchase of the building implicates the Anti-kickback Statute. Instead, it simply noted that neither the purchase of the building nor the purchase price paid was factored into its conclusion regarding the employment of the Practitioner. In so doing, the OIG effectively failed to provide guidance regarding the risks of the overall transaction.

Endnotes

[1] 42 C.F.R. § 1001.952(i).

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