

Inside CMS

exclusive news on the most powerful agency in health care

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Advocates Sue, Eye Legislation To Expand Off-Label Part D Coverage

A coalition of beneficiary advocates is pursuing a two-pronged strategy to expand off-label drug coverage in Medicare Part D: The groups are urging Congress to require that Part B rules on referenced drug compendia and scientific literature apply to Part D, and are also trying to get the courts to step in. The Medicare Rights Center (MRC) filed a lawsuit Monday (Nov. 26) challenging CMS' current off-label coverage restrictions.

MRC sued HHS Secretary Michael Leavitt in Manhattan's federal district court for preventing Part D sponsors from covering "medically necessary prescriptions" for uses not approved by FDA. "Many people with Medicare were actually better off before the drug benefit was introduced" in 2006, the complaint alleges.

The legal challenge follows an August MRC report, which highlights many advocates' concern about a growing number of off-label indications not included in the Medicare-referenced compendia.

"CMS' regulation excluding these off-label drugs from Part D coverage conflicts with the language and intent of the Medicare statutes," the group wrote at the time. "By failing to cover off-label, non-compendia uses of FDA-approved medications, the program is not meeting its intended goal of providing a 'comprehensive prescription drug benefit.'"

To illustrate its case, MRC's complaint outlines a senior's quest to

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As several senators announce opposition to cuts... OXYGEN INTERESTS BRACE FOR REDUCTIONS IN SENATE MEDICARE PACKAGE

Representatives of the medical oxygen industry are bracing for up to \$1.8 billion in proposed cuts they expect will surface as part of the Senate's imminent year-end Medicare package. What form those cuts take, however, remains a topic of speculation, as sources indicate that a lowering of the rental cap, a rate cut for stationary equipment, or some combination of the two remain on the table.

House legislation passed earlier in the year had squeezed Medicare's 36-month oxygen rental cap down to 18 months — a move estimated by the Congressional Budget Office to save \$1.8 billion over five years and \$6 billion over 10. Oxygen interests indicated earlier this month they largely anticipated

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SENATOR TAKES WEEMS TO TASK ON 1-800-MEDICARE AFTER STAFF FOUND PROBLEMS

Senate aging committee ranking Republican Gordon Smith (OR) took CMS Acting Administrator Kerry Weems to task on the 1-800-MEDICARE call-in system at a Nov. 15 hearing, charging that his staff received incorrect and misleading answers to several basic questions.

Smith, who also sits on the powerful Finance Committee, said his staffers made a series of calls to the 1-800-Medicare line and were repeatedly given false information after asking the operators several questions that should have had "scripted" answers.

"I think you need some quality control," Smith said.

Weems said he would look into the problems. CMS did not respond to a query on what has been done since the hearing.

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OIG GETS PART D DATA; MEDPAC URGES CMS TO GIVE DATA TO GAO

The Government Accountability Office (GAO) remains in a tug-of-war with CMS in its bid for access to Medicare Part D rebate and utilization data, but the HHS Office of Inspector General (OIG) has received the prescription drug data it requested from CMS, *Inside CMS* has learned.

A source familiar with the OIG data request tells *Inside CMS* that while the fraud-fighters have the Part D information they requested it is unclear if they can ever publish a report based on the data without breaking the law.

HHS lawyers have refused to hand certain data over to GAO on the grounds that the agency is not legally required to do so (see *Inside CMS*, Nov. 1). While CMS agreed to give GAO data about Part D grievances and the low-

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HHS GATHERS PART D REASSIGNMENT DATA AS STARK REQUESTS ANSWERS

Approximately 1.2 million dual-eligible Medicare Part D enrollees were reassigned a new drug plan last January because their 2006 plan's premiums moved above administratively set regional benchmarks, closely held HHS budget documents show. A powerful House Democrat is seeking similar data from CMS in response to beneficiary advocates' fear that random plan reassignments complicate access to care for vulnerable low-income seniors.

House Ways & Means health subcommittee Chair Pete Stark (D-CA) requested the data Nov. 15 in a move that may reignite his push for more beneficiary-centered, or "intelligent," Part D auto-enrollment of Medicare beneficiaries also covered under Medicaid. Stark included language in the House-passed Children's Health and Medicare Protection bill that would mandate only high-quality plans that cover 95 of the top 100 Medicare drugs — brand and generic — receive auto-enrolled beneficiaries (see *Inside CMS*, Aug. 9).

Currently, CMS randomly assigns a standard drug benefit to dual-eligible beneficiaries and reshuffles them annually unless they switch plans by themselves. Consumers Union and other advocacy groups have long urged CMS to follow Maine's lead and install a more selective auto-enrollment process that takes into account a beneficiary's drug regimen.

To assess the Medicare drug benefit's stability for its most vulnerable constituents, Stark is asking for data on how many of last year's reassigned dual-eligible beneficiaries will have to be reshuffled once more at the end of this year because of their current plan's premium hike. He also

wants to know how many low-income subsidy recipients opted out of the reassigned plan to choose another one instead.

Dual-eligible beneficiaries and others receiving the extra help may switch plans monthly, while others must generally wait for the annual open enrollment period, which runs from Nov. 15 to Dec. 31.

Stark also wants to know how many low-income subsidy recipients were "lost" and experienced coverage gaps as a result of glitches at the end of last year. The seasoned lawmaker is also asking for an update on CMS' demonstration under which WellPoint covers prescription fills for individuals who cannot be confirmed as Part D-eligible at the pharmacy counter.

HHS estimates that it has paid 86,000 claims as of Aug. 14 — at an average of approximately \$60 per claim — under that demo. Half of these were subsequently confirmed to be eligible Part D claims, according to the budget documents, meaning the total demo cost \$2.58 million, minus amounts WellPoint recouped from demo participants. An estimated 25 percent recovery rate would put the demo's cost at \$1.9 million plus administrative costs of \$317,000, CMS says.

Of the 1.174 million dual-eligible beneficiaries that were reassigned a new Part D plan on Jan. 1, 927,000 stayed with the same Part D sponsor and 247,000 were randomly assigned to another insurer, the CMS document states. CMS did not collect data on how many low-income subsidy recipients changed plans during the year, the documents state.

CMS WILL ASK CONGRESS FOR FUNDING TO IMPLEMENT ICD-10

CMS will ask Congress for about \$40 million to begin to implement a comprehensive new diagnosis coding set in 2009, according to budget documents obtained by *Inside CMS*.

When the Bush administration submits its last CMS budget request to Congress early next year, one of its priorities will be to begin to transition from the ICD-9 to the ICD-10 coding set in 2009.

The coding shift is expected to be a very expensive transition, both for the agency and for hospital, physician and other provider stakeholders.

"The process of converting from ICD-9 to ICD-10 will be a major undertaking that will include revision of instruction manuals, claims processing systems, medical software and analyses," CMS budget documents state.

A coalition of Medicare stakeholders, led by the Blue Cross Blue Shield Association (BCBSA), has urged the administration to begin the transition by updating Health Insurance Portability and Accountability Act (HIPAA) transaction standards from version 4010 to version 5010.

In June, the BCBSA, along with 29 other coalition member organizations, wrote HHS Secretary Michael Leavitt and outlined the case for moving to update the transaction standards first.

"All stakeholders agree the 5010 must be in place in order to successfully convert to ICD-10," the BCBSA coalition wrote. "And most stakeholders, including the Workgroup for Electronic Data Interchange, agree this significant change cannot be done simultaneously with ICD-10."

According to the budget documents, CMS is apparently taking the transaction standard upgrade seriously: "In order to implement ICD-10, the current version of the HIPAA transactions must be upgraded from version 4010 to 5010" to allow for the increased space required to accommodate the much larger ICD-10 code set.

On every claim submitted to Medicare, and to private insurers for that matter, diagnosis codes are attached, both for clinical and for reimbursement reasons. Under ICD-9, there are about 17,000 individual, five-digit codes. Under ICD-10, there are 12 times as many (210,000) and the codes are seven digits.

The new, longer codes can allow for a more specific diagnosis, which can help with research and patient care. The new codes can also assist fraud fighters, CMS argues in the budget documents, because the codes are so much more specific it is "easier to detect if a claim was appropri-

ately billed.” The version 10 codes can also be used to reflect the use of new technologies that ICD-9 cannot, according to CMS.

In October, Acting CMS Administrator Kerry Weems said that the hiring of the American Health Information Management Association to assess ICD-10 implementation costs, analyze Medicare policies, processes and workload associated with the replacement of ICD-9 should be seen as a signal that the agency is moving forward with imple-

mentation (see *Inside CMS*, Oct. 4).

The budget documents indicate that more than half of the funding will be used to make system modifications (\$18.1 million) and 5010 modifications (\$6.8 million). The rest will be used for planning purposes, software applications, coding books and training materials; and \$500,000 will be earmarked for contractors, which CMS estimates will see a larger volume of provider inquiries regarding the new codes.

As open enrollment period starts... **CMS ADDS MA, PART D PERFORMANCE DATA TO PLAN FINDER**

Beneficiary advocates are applauding CMS for adding Medicare Advantage (MA) and Part D performance data to its Web-based plan-selection tools in time for this year’s open enrollment period, which began Nov. 15. But they remain concerned about the tools’ usefulness, given that most plans received similar quality ratings.

CMS now rates all plans in three categories — customer service, drug coverage and pricing — as well as several subcategories, including call center wait time, beneficiary complaints and delays in handling coverage requests. MA plans are also rated on their coverage of preventative services, management of chronic conditions and access to specialists and other doctors, among other things.

The 5-star ratings are part of CMS’ long-awaited plan-specific report cards, which are linked to CMS’ two plan-selection Web sites, “Medicare Prescription Drug Plan Finder” and “Medicare Options Compare.”

CMS officials touted the added measures and greater accessibility at a Nov. 14 press conference. The data will help beneficiaries to compare their insurance options and CMS to identify plans that “we need to work with,” they said.

Beneficiary advocates — as well as several lawmakers — have long blasted CMS for what they see as lax MA and Part D oversight. Acting CMS Administrator Kerry Weems has vowed to hold the plans increasingly accountable for low performance, but many stakeholders remain skeptical.

CMS should penalize or eliminate plans that exhibit low performance, Bill Vaughan, senior policy analyst for Consumers Union, said in an e-mail. “Who would miss them in this gluttonish cafeteria of choices?” he added.

The ratings tool is far from complete. Many plans are not yet rated on several — or all — of the quality measures.

A CMS spokesperson explains: “As far as the ones without rating information, many plans are too new to report most of the measures used in the domains, and they won’t have most of the domain level scores as a result. Some plans may not have been able to report enough of the measures in a given domain for us to calculate stars for the domain. This may be due to small eligible populations, incorrect data collection, the plan not offering the benefit being measured, or not reporting certain measures. However, most plans who reported data to us reported

enough data for us to calculate domain-level stars.”

As data sources, CMS lists its Medicare enrollment records, complaints tracking module, independent review entity, Management Information Integrated Repository, Plan Finder and several consumer and health plan surveys. The agency does not reveal more specific ratings criteria.

CMS has been criticized in the past for setting up a system of performance measures that awards most plans a similarly high rating. Most plans still exhibit similar ratings in the overall performance categories, but subcategory ratings show a greater variety: Humana and several other Part D sponsors, for instance, received only one star for handling appeals after an independent review entity reviewed the insurers’ coverage decisions.

On its Web sites, CMS displays the overall categories first, and beneficiaries have to click on each category to examine rankings in the subcategories — a notion that worries advocates who fear beneficiaries will overlook the more-detailed, and variable, subcategory ratings.

A Connecticut advocate, for instance, noted that of the state’s 51 Part D plans, none received a 1-star rating in any of the overall performance categories. Only one plan, offered by HealthNet, received two stars on a cluster of measures related to the ease of filling prescriptions. Two plans, by Anthem and Health Spring, received five stars for making drug coverage and pricing data available, keeping drug prices stable and avoiding complaints about beneficiary out-of-pocket costs.

“It seems everybody is mostly ‘good’ and ‘very good,’” the advocate said in an e-mail. “[That] doesn’t really help people refine their search in any meaningful way.”

As a potential solution, Consumers Union has urged CMS to rate MA and Part D plans on a grading curve or tier plans into percentiles of performance.

“What would really help consumers [is] if the top 20 percent get five stars, the next 20 get four et cetera and you could see more clearly who is best,” Vaughan said. “The great mass of fours and some fives makes it look all kind of similar.”

CMS should also eliminate subcategories that have little to do with beneficiaries, such as a plan’s education of pharmacists, he noted.

“Why should I as a consumer be cluttered up with how long my pharmacist is on hold?” Vaughan asked. “Of course that’s important and should be reported to the

pharmacists who could decide to boycott... But at least five to six of these indicators are just background clutter to the average consumer.”

Overall, however, stakeholders appear happy with the improved plan-selection tools, the other beneficiary advocate said.

“I have to give [CMS] high marks on this. It took a while to get all the bugs out, and I still don’t understand why they ask for a beneficiary’s age and health status [before displaying plan options],” she said. “I think they’ve gotten very good about this. Everyone’s saying it’s great.”

NEW SENATE BILL REFUELS DEBATE ON QIO SCOPE OF WORK

Bipartisan legislation introduced Nov. 16 by Sens. Edward Kennedy (D-MA) and others would reform Medicare’s quality improvement program, but — unlike a proposal introduced earlier this year by Senate Finance Committee leaders Max Baucus (D-MT) and Charles Grassley (R-IA) — would keep case reviews in the hands of quality improvement organizations (QIOs). The proposals come as the White House is reviewing CMS’ draft of the next QIO scope of work.

Kennedy’s bill is cosponsored by Finance members Jay Rockefeller (D-WV), Orrin Hatch (R-UT) and Trent Lott (R-MS).

It remains unclear whether either legislative proposal will become part of the Medicare reform package Finance leaders are drafting. Grassley in particular wants QIOs to focus on helping providers improve quality of care, a source close to the issue says.

Aside from their work with providers, QIOs now also review clinical data and resolve Medicare Part A and Part B beneficiary complaints as part of the inpatient Hospital Payment Monitoring Program (HPMP). CMS, however, wants to have Medicare administrative contractors and recovery audit contractors handle the program starting next year — despite heavy opposition from QIOs and providers.

CMS wants to spend approximately \$1.2 billion on the upcoming three-year scope of QIO work, which starts next August, closely held budget documents show. That is slightly less than the approximately \$1.3 billion QIOs received during the current, 8th contract cycle.

Currently, two-thirds — or \$860 million — is being spent on core QIO contract tasks, while the rest pays for special projects, support contracts and the QIO support center, according to industry.

CMS plans to spend \$383.5 million of \$474.5 million in QIO monies on core contract activities in fiscal 2008,

according to the budget documents obtained by *Inside CMS*. In fiscal 2009, when many new QIO contracts will be awarded, \$470.1 million of \$548 million should go toward core contract activities, CMS says.

CMS plans to award 19 state-based QIO contracts on Aug. 1, 2008. Seventeen additional ones will be finalized in November, and the remaining 17 will follow before the end of that year, CMS says.

Providers and the American Health Quality Association (AHQA), which represents QIOs, are concerned about CMS’ plan to shift HPMP to recovery audit contractors because they fear that these contractors, which are paid to retrieve Medicare overpayments, will be biased or unable to handle clinical case reviews (see *Inside CMS*, Nov. 1).

The Baucus-Grassley bill, introduced Aug. 2, would also strip QIOs of their current HPMP duties, prompting AHRQ to endorse the Kennedy bill instead.

Still, the group has several gripes with the Kennedy language. For instance, the bill asks the Institutes of Medicine to determine how much money should go to locally determined projects; AHRQ would prefer Congress to specify that 20 percent should go to these projects, as the House has advocated.

But, AHRQ argues, the bill does accomplish Grassley’s objective of making QIOs more accountable to CMS and beneficiaries. Grassley had questioned QIO work ethics last year after criticizing what he called a low number of beneficiary complaints QIOs handle annually. QIOs argue that they handle all incoming complaints, but that many beneficiaries don’t know about their right to complain because the current QIO scope of work does not include funding for outreach activities.

The Kennedy bill would allot funding for outreach and improve QIOs’ ability to give progress reports to complaining beneficiaries.

SUBSCRIPTIONS:

**703-416-8500 or
800-424-9068
custsvc@iwppnews.com**

NEWSOFFICE:

**703-416-8577
Fax: 703-416-8543
insidecms@iwppnews.com**

Health Group Publisher: Donna Haseley
Managing Editor: Brett Coughlin (bcoughlin@iwppnews.com)
Associate Editors: Rolf Rosenkranz (rolf.rosenkranz@iwppnews.com)
Mike Lillis (mlillis@iwppnews.com)
Amy Lotven (alotven@iwppnews.com)
Production Manager: Lori Nicholson
Production Specialists: Daniel Arrieta, Sharonel Salvacion, Andrew Leonard

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CMS says students too wealthy to need low-income benefit

BILL WOULD EXTEND MEDICAID DRUG DISCOUNT TO COLLEGE HEALTH CENTERS

Legislation to tweak Medicaid's drug rebate program to restore large discounts on contraceptives purchased by university health centers was introduced in both chambers of Congress this month. Supporters say the move would reduce the number of unintended pregnancies among the nation's college students, but CMS maintains that, generally speaking, such students are too wealthy to merit inclusion in a benefit intended for low-income patients.

Proponents of the legislation hope it will surface as part of the Medicare package currently being crafted by Senate leaders.

At issue is Medicaid's nominal price exception (NPE), which Congress created in 1990 as part of CMS reforms included in the Omnibus Budget Reconciliation Act. The intent was to align Medicaid pricing more closely with that of private purchasers while also providing pharmaceutical makers with incentives to lend steep discounts to charitable organizations and other safety net providers.

Under the law, drug makers willing to sell their branded products at less than 10 percent of the average manufacturers price are not penalized with huge increases in the Medicaid rebates they owe to states. Because the drug companies pick up the tab, there is no additional cost to the states or the federal government. For years, university health centers took advantage of the savings.

But abuse of the NPE prompted Congress to limit the types of entities eligible for the discounts. In the 2005 Deficit Reduction Act (DRA), lawmakers cited four qualifying groups — state-owned or operated nursing homes; intermediate care facilities for the mentally retarded; 340B facilities; and any other entity HHS deems appropriate — but excluded university health centers.

Student health advocates had hoped that CMS, through the regulatory process, would expand eligibility to university clinics this year. But, in a final rule published in July, the agency declined to do so.

"We considered using this authority to expand this exclusion to other safety-net providers," the final rule states. "However, we believe that the entities specified in the statute are sufficiently inclusive and capture the appropriate safety net providers."

A CMS spokesperson defended that decision this week, maintaining that the NPE is not appropriate for college students.

"We did not feel that university clinics met the definition of safety-net providers," the spokesperson said, adding that in the eyes of the agency, the benefit was intended to cater to low-income, uninsured patients — "a Medicaid-like population."

"[College students] are not, for the most part, impoverished," the spokesperson noted.

The DRA provision went into effect at the start of 2007, causing the price of branded contraceptives on many university campuses to skyrocket. Mary Hoban, director of the national college health assessment program at the American College Health Association (ACHA), said that

monthly regimens once available for between \$5 and \$12, are now running between \$40 and \$50 on many campuses.

An estimated 3 million college women currently take oral contraceptives, according to Planned Parenthood.

And while some students have had luck moving to generics, Hoban added, those alternatives are more expensive than the branded drugs under the previous discount program.

"Some students are not able to afford that increase and are going without," she said.

A representative of the National Organization for Women said that access to contraceptives is the primary issue on university campuses these days — largely due to the new NPE exclusion. "The cost has just jumped incredibly in recent months," she said.

The practical effects of the DRA provision vary from campus to campus, said a source with Planned Parenthood, as some schools stockpiled the drugs before the DRA provision took effect. But those reserves are running thin, and many schools say they're feeling the sting.

Polly Wheat, director of the Student Health Service at Columbia University, said the student cost for one contraceptive device — the Nuva Ring — has jumped 1,000 percent since the new law took hold.

Citing tales like Wheat's, lawmakers in both chambers are pushing for change. The Senate bill, introduced Nov. 13 by presidential hopeful Barack Obama (D-IL) and Claire McCaskill (D-MO), would clarify that university health centers are eligible for the NPE benefit.

"No woman should be turned away from university clinics and health centers because the cost of prescription drugs is out of reach," Obama said in a statement.

Among the Senate co-sponsors are Finance Committee Chair Max Baucus (D-MT) and a handful of additional committee Democrats, including Jeff Bingaman (NM), John Kerry (MA), Ron Wyden (OR), Charles Schumer (NY), Debbie Stabenow (MI) and Maria Cantwell (WA).

Similar House legislation was introduced Nov. 1 by Rep. Joseph Crowley (D-NY). That bill currently has 123 co-sponsors, including Ways & Means health subcommittee Chair Pete Stark (D-CA).

Supporters of the legislation have tried without success to attach similar language to a number of vehicles this year, including a bill to reauthorize a popular children's health program and another to grant emergency funding for the wars in Iraq and Afghanistan.

A Crowley spokesperson said the language has its best chance to move as part of a large Medicare package currently being negotiated by Senate Finance Committee leaders. The committee is tentatively planning to mark up that package on Dec. 5, sources say (see related story).

Meanwhile, drug makers are generally supportive of expanding the NPE discounts to college students — an attractive public relations move that has the dual advantage of introducing young consumers to a product they might stick with long after graduation. For that reason, some critics have accused companies of efforts to "hook"

students on a brand for which they (or their insurance providers) will have to pay the full price after the students leave school.

A spokesperson for Ortho Pharmaceuticals, a subsidiary of Johnson & Johnson and one of the nation's top producers of oral contraceptives, would not describe the company's incentives in offering the discounts, except to say that it is "committed to serving the under-served community."

A spokesperson for Barr Pharmaceuticals Inc., another large producer of the drugs, echoed that sentiment, claiming the company granted the university discounts

"because it was the right thing to do."

Still, at least one key skeptic has vowed to keep a close eye on the arrangement. According to a CBS report, Sen. Charles Grassley (R-IA) said last month, "We can't encourage pharmaceutical companies trying to get people or pharmacists hooked on their drug with the idea that they'd be selling more of it later on."

That statement does not preclude the possibility that university health centers were dropped from the NPE benefit unintentionally, Grassley's office said last week, but the Iowan has yet to solidify his position.

Baucus, Grassley had pushed for CMS plan

CMS PROPOSES SHIFT TO HOSPITAL PAY-FOR-PERFORMANCE OVER 3 YEARS

In its latest effort to link Medicare payments to quality, CMS this week proposed that Congress cut hospital baseline payments while lending facilities the chance to "buy back" the losses by meeting certain performance or improvement measures. The long-awaited plan on value-based purchasing (VBP), issued to Congress Monday (Nov. 26), would phase out CMS' current pay-for-reporting system and replace it over three years with a model based fully on performance.

But the report — a mandate of the 2005 Deficit Reduction Act (DRA) championed by Senate Finance Committee Chair Max Baucus (D-MT) and ranking Republican Charles Grassley (IA) — provides only broad recommendations for Congress in areas that would require statutory changes to enact. That has caused some observers to wonder how quickly the move to pay-for-performance will materialize.

"The paper is chock-full of options, so Congress has some choices to make," said a Washington attorney familiar with the report, noting that partisan agreement has been rare this year.

In a statement issued Monday, Grassley did not comment specifically on the recommendations, but stressed the importance of adopting a pay-for-performance system under Medicare.

"Now that the plan is set, Congress needs to get the job done and pass additional legislation to start implementing value-based purchasing," Grassley said.

Under the proposal, hospitals would see across-the-board cuts between 2 and 5 percent for each diagnosis related group (DRG) payment, which facilities could then "buy back" with high performance marks, CMS officials said in a conference call Monday. Performance measures could be grouped into domains such as clinical process-of-care (for example, appropriate antibiotic selection for pneumonia patients) and efficiency measures, CMS noted.

To include low-performing hospitals, CMS proposes a system of evaluating each measure based on an "attainment score," determined by current performance, or an "improvement score," comparing a hospital's current score with its previous performance.

CMS Acting Administrator Kerry Weems heralded the plan as "a milestone" in the agency's effort to pay for Medicare services based on quality.

Weems said the potential savings to Medicare would

hinge on whether lawmakers chose to redistribute all of the DRG reductions to well-performing hospitals, or to retain some for other purposes. The plan "could be [a savings tool] if that's the way Congress implemented it," he said, adding, "We're hopeful they can make it back through performance. That's the heart of pay for performance."

Several industry groups agree. Premier healthcare alliance, which is currently participating in a CMS quality demonstration, applauded the agency's move toward pay-for-performance — so long as the savings remains in the hospital arena.

"We believe a Value Based Purchasing plan should reward hospitals for quality gains and not be used as a cost-cutting program," a Premier representative said in a statement.

The American Hospital Association weighed in with a similar message, noting that Congress can take the plan in any number of directions, and it remains "unclear how or if [the 2 to 5 percent cut] would be returned to hospitals."

The Washington attorney noted an additional concern among hospitals: The quality measures presented in the plan hinge almost exclusively on the decisions of physicians, the source said, while the financial incentives target hospitals. Without aligning the incentives for both groups — either through a system of gainsharing or otherwise — the pay-for-performance model will be more difficult to install, the source added.

The senior lobby weighed in with generic support for pay-for-performance, as AARP issued a statement commending the move as "both common sense and necessary to ensure that health care does not continue to become increasingly unaffordable for Medicare beneficiaries over time."

Weems said the agency supports a strategy to phase in the VBP structure over three years, with CMS basing the first year's payments on reporting, the second year's payments on a 50/50 split between reporting and performance, and the third year's payments on performance only.

Later in the call, Weems clarified that that particular model represents "the way it could work, as an example."

The DRA had mandated that CMS issue its VBP plan earlier in the year. Weems said Monday that the delay stemmed from the complexity of the issue.

"We wanted to make sure that what we sent to the Congress is right," he said.

CMS SUED OVER OFF-LABEL RESTRICTIONS . . . begins on page one

retain coverage for Cetrotide to treat ovarian cancer. Her Part D plan denied coverage in early 2006, and CMS' independent review entity upheld the denial because Medicare-referenced drug compendia do not list Cetrotide use in patients with ovarian cancer. An administrative law judge later recognized peer-reviewed evidence in support of the off-label indication, but still ruled against the beneficiary because, he said, peer-reviewed journals are only allowed as evidence in Part B, not Part D. The Medicare appeals council then did not prioritize the case because, unlike with Part A and Part B, it is not required to review Part D cases within 90 days.

MRC wants the Manhattan judge to rule that a drug need not be prescribed for a "medically accepted indication" to be a "covered Part D drug." Such a ruling could compel Part D plans to accept evidence from medical journals in support of a beneficiary's request for off-label coverage.

"I don't think the compendia should be the last word," one source close to the issue said. A policy change would affect only a "small subset" of coverage appeals, he added.

Advocates are also pushing legislation that would align Part D rules on off-label coverage with Part B's. They failed to attach language to the House-passed Children's Health and Medicare Protection bill earlier this year, but are hoping Senate Finance Committee leaders will include it in a Medicare reform package in the coming days or weeks.

Under the proposal, peer-reviewed literature would be allowed as evidence in Part D, and CMS would have to periodically update its list of Part D drug compendia.

CMS proposed to install an annual process for

updating its list of Part B-referenced compendia in July.

In October, CMS also added 11 peer-reviewed journals to its list of references that may be used to justify off-label Part B coverage for oncology treatments. The move drew the attention of ranking Senate Finance Republican Charles Grassley (IA), who raised questions about the independence of CMS-referenced medical journals in a Nov. 7 letter to Acting CMS Administrator Kerry Weems.

Most peer-reviewed journals don't have policies aimed at minimizing conflicts-of-interest and may thus be susceptible to bias, Grassley argues. It is unclear whether he is considering legislation that would restrict CMS' use of medical journals to those that have strong conflict-of-interest controls.

More than 20 percent of prescriptions written for the 500 most commonly used drugs are for off-label uses, MRC says in its complaint filed with the Manhattan federal district court. The number is even higher for oncologists: More than 60 percent of all cancer treatment is administered off-label, advocates say.

Advocates have long complained about the time it takes beneficiaries to navigate the Part D appeals process, and they are particularly concerned about the coverage of expensive anti-cancer treatments, which are often administered off-label. At this point, however, the coalition of advocates is not seeking legislation to tighten deadlines for the review of Part D enrollees' coverage appeals.

The coalition urged Finance Chair Max Baucus (D-MT) in a Nov. 15 letter to help improve off-label coverage in Part D. The letter was signed by several HIV-AIDS and cancer groups, as well as members of Medicare Access for Patients Rx, a coalition that includes the National Health Council and Mental Health America.

CMS LAUNCHES IMAGING EFFICIENCY PILOT PROGRAM

In what a Washington insider indicated could be a move away from the "meat ax" style of imaging cuts included in the 2005 Deficit Reduction Act (DRA), CMS last week announced it has contracted with L & M Policy Research Group and its partners to develop efficiency measures for the imaging industry. The agency will collect stakeholder comments on the four draft measures through Dec. 14.

The pilot represents a "utilization management" strategy rather than the across-the-board cuts included in the DRA, but the goal is "clearly to reduce imaging use and spending," the source said.

The idea of a radiology benefit manager system was one that Rep. Nathan Deal (R-GA) championed when he was chairman of the Ways & Means health subcommittee, but that never really gained traction.

The four initial efficiency measures to be studied include lumbar MRIs for lower back pain, mammography follow-up rates and the use of contrast materials in abdomen and thorax CTs.

The initiative was spurred by Medicare Payment

Advisory Commission data indicating that diagnostic imaging is the fastest growing segment of Medicare spending on physician services. Volume and complexity grew by 9.9 percent per year on average between 1999 and 2003, nearly twice the rate for all physician services during the same time period.

"By developing a set of measures to document the prevalence and variation in efficiency of imaging services, CMS can develop program guidance and policies to ensure that high quality, appropriate care is delivered with minimum waste," states a Web site (www.imagingmeasures.com) created to collect comments on the new measures.

The study will be "driven by clinical evidence, tested on both commercial and Medicare claims data, and pilot tested in a sample of different provider settings to validate real-world feasibility," according to the Web site.

An L & M representative referred a query about the program to a CMS official who did not respond by press time.

The American College of Radiology (ACR) is putting

together a consolidated response to the draft measures, and urging its members to submit comments as well. An ACR representative said that CMS officials provided assurances that there is no intention to use these measures for programs such as the Medicare Physician Quality Reporting Initiative in the foreseeable future.

A source with the Access to Medical Imaging Coalition, which has been working to fight industry cuts, expects several members will comment on the initiative, but did not elaborate. Several other industry sources did not respond to queries by press time.

After examining inconsistent drug measurement...

OIG WARNS OF INCORRECT MEDICAID REBATES, PHARMACY REIMBURSEMENT

Inconsistent drug measurement may lead to incorrect Medicaid rebate payments, disputes with manufacturers and, starting next year, incorrect pharmacy reimbursement, the Office of Inspector General (OIG) says in a report released Nov. 15. CMS dismisses the concerns and accuses HHS' legal watch dog of "oversimplifying" the complex issue of measuring and converting drug units.

States use National Council for Prescription Drug Programs (NCPDP) unit-of-measure standards to calculate drug-specific pharmacy reimbursements before collecting statutorily defined rebates from manufacturers that are based on different unit measurements, set by CMS. To avoid inconsistencies, states must convert utilization data from NCPDP units to CMS units, the OIG says.

But, according to the OIG, states convert less than half of their utilization data for drugs with unit-of-measure inconsistencies, which resulted in an estimated \$8.1 million in underclaimed and \$3.7 million in overclaimed Medicaid rebates in the first half of 2006. Most inconsistencies were identified for treatments that are not measured by volume or weight, such as tablets, capsules and suppositories.

CMS and OIG agree that drug measurement errors account for less than 1 percent of total Medicaid rebates billed. In a pointed response to the report, CMS stresses that state officials agreed at a fall meeting on the Medicaid drug rebate program that unit-of-measure errors are "not widespread, result in little financial impact, and are easy for the States to detect and correct through the invoice adjustment and dispute resolution process."

The OIG "oversimplifies" the issue of unit-of-measure

CMS' efficiency initiative comes as stakeholders work furiously to protect the industry from another round of cuts. The DRA cut billions from Medicare providers, and interested parties are worried additional cuts may show up in the Finance Committee's upcoming Medicare package (see *Inside CMS*, Nov. 15).

The imaging lobby has struggled with CMS to define what types of diagnostic services are considered "appropriate" and to educate Congress about the health benefits of imaging technologies like positron emission tomography.

conversions, CMS says while pledging to continue to address emerging problems on a case-by-case basis. The agency is unable to provide manufacturers with a detailed framework or analytical process for resolving unit-of-measure discrepancies because, CMS says, FDA approves drugs and their packaging differently from one national drug code to the next.

The OIG found that states tend to prioritize the highest-value inconsistencies, but that they often cannot correct them because of lacking CMS guidance and incorrect manufacturer-reported package sizes. HHS' legal watch dog recommends CMS provide more specific guidance to manufacturers and states, and post on its Dispute Resolution Program Web site all unit-of-measure inconsistencies identified by CMS, states and manufacturers.

If not addressed, the inconsistencies may affect pharmacy reimbursement starting next year, when a new definition of drug-specific average manufacturer prices (AMPs) is scheduled to take effect unless Congress answers the pharmacy lobby's call and intervenes, the OIG cautions.

CMS' final rule, published in early July, as well as legislation introduced to trump it, is expected to prompt states to tie pharmacy reimbursement to a drug's AMP. But because AMPs are based on CMS' unit-of-measure standard, using AMP to determine appropriate pharmacy payments will require that states convert reimbursement units into the NCPDP standard used in the retail market, the OIG argues.

DURBIN, BURR PUSH FOR CMS DEMO ON MEDICAID/SCHIP CASE MANAGEMENT

A bipartisan Senate duo is calling for CMS to launch a demonstration program aimed at helping Medicaid and State Children's Health Insurance Program (SCHIP) beneficiaries who visit numerous providers maintain a steady course of care. The Medical Homes Act, introduced Nov. 16 by Majority Whip Richard Durbin (D-IL) and North Carolina Republican Sen. Richard Burr, would allow CMS to pay participating primary care doctors a monthly fee to manage and coordinate care with other health care providers.

"At a time when both health care costs and chronic illnesses are on the rise, we need a better way to provide care that is accessible, comprehensive, coordinated, continuous, and cost-effective," Durbin said in a release.

The legislation, if passed, would require CMS to initiate a three-year demonstration program in eight states — four which already provide primary care case management and four which do not — by October 2009. States would receive grants to launch the program and would have to agree to pay participating primary care providers at

least \$2.50 per month per beneficiary to subsidize the extra costs since it is expected that the primary care physician would increase usage of health staffers, such as case managers, who often arrange transportation, follow up with patients after emergency room visits, send reminders about flu shots and expedite provider referrals. The provider payments would be eligible for federal Medicaid matching funds.

Burr noted that in his home state a coalition called Community Care of North Carolina (CCNC) has been successful in offering a “one-stop shop” for medical care. According to the “findings” included in the legislation, a recent study found that the CCNC saved the Medicare program \$244 million in 2004, and similar amounts in 2005 and 2006.

The Senate proposal has no other co-sponsors, and it does not have a companion bill in the House. A Durbin staffer said, however, that other lawmakers may be trying to move a similar concept for Medicare patients and, if that moves, “we will try to do the same for CHIP and Medicaid beneficiaries.”

It is unclear which concept the aide was referring to. Sen. Blanche Lincoln (D-AR), a member of both the Special Committee on Aging and the Finance committees, intro-

duced legislation that promotes chronic care management in Medicare. The Geriatric Assessment and Chronic Care Coordination bill has 12 co-sponsors, including Finance member John Kerry (D-MA) and Democratic presidential hopeful Hilary Clinton (NY). That bill has mirror legislation in the House, introduced by Rep. Gene Green (D-TX), and has 10 co-sponsors.

A congressional staffer confirmed that Lincoln is working to get a demonstration version of her bill into the Medicare package expected to be marked up by Finance in December.

However, the aide pointed out that while the medical home bill incorporates some of the same concepts, the chronic care bill is focused specifically on Medicare beneficiaries with multiple chronic conditions who often have very complex care needs resulting in high costs to the Medicare program. “Sen. Lincoln believes that by targeting those beneficiaries, we can really demonstrate value built upon a comprehensive geriatric assessment and coordination of care by providers,” the staffer said.

It’s unclear at this late stage in the session, and with a presidential election year looming, whether either of the stand-alone bills will gain traction by the end of the year.

OXYGEN LOBBY READIES FOR CUTS . . . begins on page one

the Senate to include similar language in the legislative package currently being negotiated by Finance Committee leaders, but industry sources have said more recently that other savings options have surfaced as part of those talks.

The Finance Committee is “very seriously considering” an across-the-board cut in rates for stationary oxygen equipment, a source representing pulmonary interests said Tuesday. Those rates currently average around \$198 per month, but there is talk they could be slashed by \$43, the source said. It remains unclear, however, if such a proposal would constitute a straight cut, or whether a portion of those dollars would be redistributed within the oxygen arena, the source added.

A Washington-based health policy observer suggested the source of the cut matters little. “It doesn’t make any difference from a point of view of cash in pocket,” he said.

That sentiment has been echoed by some of the larger players in the oxygen industry, who have refrained from weighing in too heavily on the speculative details of the expected cuts, preferring to focus their opposition on any cuts at all.

Those pleas have not gone unnoticed in Congress, where legislation introduced in both chambers this year would repeal the 36-month rental cap altogether.

More recently, five senators urged Finance Chair Max Baucus (D-MT) and ranking Republican Charles Grassley (IA) to remove oxygen cuts from the table of offsets negotiators are considering in their Medicare package.

“Additional cuts to the Medicare oxygen benefit could not only increase costs to the Medicare program in the

form of increased hospitalizations, but could also present substantial health risks to over half a million Medicare beneficiaries,” the lawmakers wrote in a Nov. 19 letter. Signing the message were Sens. George Voinovich (R-OH), Tim Johnson (D-SD), Johnny Isakson (R-GA), Susan Collins (R-ME) and Sheldon Whitehouse (D-RI).

Lobbyist sources anticipate other differences between the House and Senate oxygen proposals. The House bill, for example, would have transferred the title of the oxygen equipment over to patients at the end of the 18-month rental period, as is currently the case after 36 months. Industry, wishing to recover the equipment following its disuse by a particular patient (due to either health improvements or death), had pushed to keep ownership with the provider. Stakeholders widely believe the Senate bill will repeal the title transfer.

Additionally, the House legislation exempted oxygen generating portable equipment (OGPE), which would have remained subject to the 36-month rental cap. Industry hopes the Senate will retain that exemption, but sources are wary it will be removed.

Medicare currently pays for OGPE at about \$52 per month as an add-on to the stationary equipment reimbursement.

Some stakeholders are also hoping Finance leaders will adopt beneficiary retesting language, which aims to reevaluate new Medicare oxygen patients after 60 days to weed out those no longer in need of the benefit. According to one industry estimate, if 5 percent of new patients were removed from oxygen through retesting, Medicare could

save about \$200 million over five years.

Payments to home oxygen have been a topic of controversy for at least the past decade. The 1997 Balanced Budget Act cut rates by 25 percent in 1998 and clipped another 5 percent a year later. In 2005, responding to an HHS Inspector General report comparing Medicare rates to those paid by federal employees' health plans, CMS made additional cuts averaging 8.6 percent for stationary equipment and 8.1 percent for portable equipment.

More recently, CMS launched its competitive bidding program for durable medical equipment (DME), which will likely lead to further oxygen reductions. That program will affect 10 metropolitan areas next summer and 80 in 2009. Afterwards, CMS has the option to expand the experiment even further.

In the midst of the cuts have come signs that Medicare continues to overpay. Another HHS report issued last year found that renting an oxygen concentrator for 36 months costs Medicare about \$7,215 for a device with an average retail value of \$587 (see *Inside CMS*, Sept. 21, 2006).

Industry blasted the report, saying it failed to consider service and other costs. "The provision of oxygen in the home is for a therapy, not just a piece of equipment," a DME source said recently.

But House Democrats rejected that argument earlier this year, justifying the 18-month cap with the explanation that "[t]here is absolutely a cost to the service component that goes along with the provision of the equipment, but there is no evidence that service totals more than \$6,600 in thirty-six months."

Industry also points out that many of the cuts already enacted have not yet been implemented. The 36-month

rental cap, for example, went into effect at the start of 2006, meaning that the earliest financial impact will not be felt until 2009. An industry-commissioned Avelere study issued in July estimated that, as a result of the rental cap and competitive bidding program, Medicare cuts to oxygen would hover around \$700 million in 2009.

"They are not accounting for [these cuts]," a source representing the Council for Quality Respiratory Care, a trade group, said in reference to lawmakers eying oxygen for further savings this year.

The House oxygen provision accompanied the chamber's efforts to renew the State Children's Health Insurance Program (SCHIP), but, like most others related to Medicare, it was stripped from the bill during negotiations with Senate leaders who wanted to address SCHIP separately.

That puts all eyes on Senate leaders, who have vowed to pass their Medicare package before year's end, but remain in disagreement over how to pay for a 10 percent physician cut slated to take hold Jan. 1 (see related story).

Meanwhile, Senate Minority Whip Trent Lott (R-MS), a vocal supporter of the oxygen industry and Finance Committee member, shocked Washington Monday (Nov. 26) by announcing his retirement at the end of this year's congressional session. Lott's departure opens a space on the committee, leading to some hope within the oxygen industry that Voinovich, who unsuccessfully sought an empty Finance seat earlier in the year, would fill the spot. The seat was ultimately taken by Nevada GOP Sen. John Ensign. Several sources have indicated, however, that Sen. Mike Enzi (R-WY) will get the nod instead.

No one was answering phones in Voinovich's Washington and local offices Tuesday or Wednesday. Calls and e-mails to Enzi's office were not returned.

"[T]here is absolutely a cost to the service component that goes along with the provision of the equipment, but there is no evidence that service totals more than \$6,600 in thirty-six months."

— from the W&MS report on CHAMP

SENATE HEALTH COMMITTEE HOPES TO MOVE HEALTH INFO TECHNOLOGY BILL

There is a late surge of activity in the Senate aimed at moving the revamped Wired for Health Care Quality Act (S. 1693) before the end of the year. The goal is to either connect it to a Medicare package (see related story) or "hotline it" — that is, try and gain passage through unanimous consent, a lobbyist familiar with the negotiations said.

The bill, sponsored by Senate health committee Chair Edward Kennedy (D-MA) and ranking GOP member Michael Enzi (R-WY), has 12 co-signatories that include two presidential candidates: Sens. Hillary Clinton (D-NY) and Barack Obama (D-IL).

The lobbyist said that staff for the health and Finance committees have ironed out issues concerning Medicare jurisdiction. Meanwhile, the bill has been redrafted in a bid

to allay the concerns of patient privacy advocates and Senate Judiciary Committee Chair Patrick Leahy (D-VT).

Health committee staff met with physician lobbyists and specialty society representatives Nov. 27, the lobbyist said, and are considering the physician reps' concerns, which hinge on allowing clinical data, instead of just claims data, to be used as the basis of quality reporting on physicians. Physicians want a hand in writing the reports and say they should be allowed to work with quality reporting entities on risk adjustment of their services.

The bill would establish a road map to national interoperability, establish the Office of the National Coordinator of Health Information Technology and provide three types of grant programs to encourage adoption of health IT.

SMITH PROBES 1-800-MEDICARE . . . begins on page one

In addition to receiving inaccurate answers, Smith's staff had a hard time getting their phone calls connected. A Smith staffer said that for the 15 test calls placed "not a single call" connected to the system in less than 14 minutes and one took 31 minutes.

"Senator Smith was dismayed by the disparate responses to questions that should have fairly standard, scripted answers," the staffer said in an e-mail responding to an *Inside CMS* inquiry. The e-mail points to what staff view as "the more troubling responses received by the staff — some of which were at best misleading, and at worst flat out inaccurate."

According to the e-mail, call center customer service reps told the Smith staffers that: 1. Beneficiaries can switch plans at any time if they don't like the plan in which they enrolled; 2. Not liking the plan might be on the list of reasons for which a special enrollment period is granted; and 3. All Medicare Advantage plans offer drug coverage.

Explanations about the late enrollment penalty, as well as the enrollment period for Medicare Advantage, were grossly inconsistent, the staffer said. Worse, in one instance, a representative asked for a "beneficiary's" zip code, and without any additional information, such as which medications the person takes, the official provided the name of a specific plan that would be "best" for someone living in that area. The aide was unable to disclose the name of the plan that was offered due to an ongoing investigation.

Presented with the information from Smith's office, the seniors group AARP immediately blasted the findings.

"Medicare beneficiaries rely on 1-800-Medicare as the primary source of information about the program — particularly during the Part D annual open enrollment," AARP spokesperson Drew Nannis said. "This service needs to be a source of unbiased and accurate information. The information presented by Sen. Smith was deeply concerning. CMS must do more now to ensure that 1-800-MEDICARE is an unbiased and accurate source of health care information. If the agency is unable do this then Congress needs to take action."

As far as next steps, the aide said that Smith has directed the staff to continue to make test calls, and has asked CMS to provide him with information on call handling and staff training as well as CMS' monitoring and auditing procedures. Staffers plan to visit CMS call centers during the open enrollment period — which started Nov. 15 and will continue through Dec. 31 — to meet with call center management and review calls. Smith also plans to ensure that the call centers are appropriately funded and staffed.

The 14-or-more minute wait time reported by the congressional staffers is more than 50 percent greater than the eight-to-nine minute average wait time CMS is targeting for fiscal 2009, according to HHS budget documents obtained by *Inside CMS*. The documents note that in order to achieve an average wait time of eight minutes during peak call time — November to January — and nine minutes during off-peak time, call center operations must be funded at \$178.1 million.

The documents point out that while the average time is eight or nine minutes, some calls could be picked up from 0 to 15 seconds. HHS also plans to implement a 15-minute wait time cap, and implement a call back program.

Other groups, like Consumers Union, remain concerned about the quality of the telephone help services offered by private Medicare Part D plans. "Some of the quick telephone response times listed on the Medicare quality web site seem questionable, given the anecdotal reports we've received, and we hope Congress will investigate the accuracy of that data," Consumer Union analyst Bill Vaughan said in an e-mail. "In addition, the way that Medicare rates the plans for quality fails to give consumers easy-to-use information on what is the best and worst of the plans in a state."

Smith's comments to Weems came two months after House Ways & Means health subcommittee Chair Pete

Stark (D-CA) ripped CMS and Weems for failures outlined in an HHS OIG investigation of the call center system.

The report found that 21 percent of callers hang up before getting their answers, and 29 percent were not satisfied with the answers they received. The report also found that the satisfaction rate has dropped since the OIG's 2004 review.

"You, your predecessors and President Bush have repeatedly argued that our health care system should 'pay for performance,'" Stark wrote in a Sept. 28 letter. "I therefore write you to inquire if CMS will continue to pay the private contractor who currently runs 1-800-Medicare for their substandard performance or seek a new contractor who can better serve Medicare's beneficiaries. If CMS intends to retain the current contractor, what measures are the agency and the private contractor taking to improve the accuracy, completeness, and timeliness of call center responses?"

Arlington-based Vangent, Inc.— formerly Pearson Government Solutions — is currently the sole provider of the 1-800-Medicare service.

Stark on Sept. 25 asked the Government Accountability Office (GAO) to investigate key aspects of the call center customer service, including wait times and ability to assist non-English speaking beneficiaries. He also asked the GAO to look into CMS' oversight of the call center.

***"This service needs to be a source of unbiased and accurate information."
— an AARP spokesperson***

VELÁZQUEZ VOWS TO IMPROVE LAW ON SMALL BUSINESS ANALYSES

House Small Business Committee Chair Nydia Velázquez (D-NY) wants to strengthen the Regulatory Flexibility Act (RFA) to prevent government agencies from claiming policy changes have limited impact on small business unless they have evidence to back up the claims. The plan could compel CMS to release key data when drafting rules, including on the agency's calculations on upcoding that have led to highly controversial Medicare provider cuts this year.

Regulators have "exploited weaknesses" in the law to, for instance, avoid releasing sufficient proof when certifying a rule will have no significant economic impact on small businesses, Velázquez said at a Nov. 15 hearing to examine agency compliance with the RFA.

"While agencies are required to provide a factual basis for such certification, they often provide only a simple statement which dismisses the concerns of small firms," Velázquez said. "This behavior must stop and we will be seeking legislative means to prevent this."

Velázquez indicated she may also seek legislation to require that agencies consider the impact on small businesses that are not directly regulated by a rule, and to specify how and when agencies must periodically review the impact of existing rules.

Ranking Republican Steve Chabot (OH) said: "Efforts led by the President, the Office of Information and Regulatory Affairs, and the Chief Counsel for Advocacy resulted in improving agency compliance with the RFA. However, they continued to be hindered by bureaucrats that seek to perform the minimum amount of analysis possible and courts that seek to abet them in those efforts."

Although the hearing did not focus on CMS, one witness complimented the agency for improving its RFA compliance. But CMS can still do better, said William Dombi, the National Association for Home Care & Hospice's (NAHCH) vice president for law.

Dombi urged Congress to expand the RFA so that it

covers interpretative policies and guidelines — a request that may have been prompted by what some Washington experts call the federal government's increasing use of "subregulatory" guidance to avoid lengthy comment periods. Dombi also wants lawmakers to set uniform standards for how agencies should examine the impact of all policy options, and to amend the Congressional Review Act so that Congress can challenge elements of a rule that do not affect an agency's broad regulatory scheme.

CMS released few details earlier this year when citing anticipated upcoding as the reason for next year's 2.75 percent payment reduction faced by Medicare home health providers, Dombi said. CMS has yet to release the technical report that outlines the agency's analysis, he added.

"Under Medicare law, a rate adjustment is authorized only to the extent that case mix weight changes are unrelated to changes in patient characteristics," Dombi said. "NAHC's analysis showed significant changes in patients receiving home health services such as higher incidence of knee replacement patients and patients of advanced age. In comparison, CMS alleged that all the change in case mix weight scores was unrelated to changes in patient characteristics."

CMS also cited anticipated upcoding as a reason for cutting 2008 hospital payment cuts, although Congress reduced the cut as part of a health-extendors package President Bush signed Sept. 27 (see *Inside CMS*, Oct. 4).

Several other recent CMS rules have drawn fire from small business advocates, including those on defining drug-specific average manufacturer prices, implementing a laboratory competitive bidding demonstration, and requiring durable medical equipment suppliers to post surety bonds to ensure that Medicare can recover up to \$65,000 in erroneous payments that result from fraudulent or abusive billing practices (see *Inside CMS*, Sept. 20).

FINANCE COMMITTEE TO MARK UP MEDICARE PACKAGE

The Senate Finance Committee is shooting for a Dec. 5 markup for the much-anticipated Medicare package it has been drafting, but staff-level discussions have not yielded an agreement on content, sources tell *Inside CMS*.

Finance Chair Max Baucus (D-MT) and ranking Republican Charles Grassley (IA) met the morning of Nov. 16 to discuss the matter and have reached a tentative agreement to hold a markup.

Sen. Ron Wyden (D-OR) indicated later in the day that the two had reached an agreement to proceed to a markup, but was unable to provide details on the content.

Several sources indicated that there continues to be no deal on the substance of the package, but said the markup has been tentatively scheduled for Dec. 5. If lawmakers are unable to come closer on a deal, one source noted, the hearing could quickly be postponed until later in the month.

In the meantime, Finance staff have been working over the Thanksgiving break to iron out the not insignificant policy differences among members. Democratic and Republican Senate staffers met throughout the recess and are hopeful that they can present members with a deal when they return to Washington next week.

Baucus has said repeatedly that he wants to push for a two-year physician fee fix, while Grassley has indicated that disagreements over offsets, most notably surrounding cuts to Medicare Advantage plans, will most likely force lawmakers to fall back on a one-year fix.

A Baucus spokesperson would not confirm the markup date, but said members intend to move on the legislation "shortly" after returning from the Thanksgiving recess.

"We still have work to do on the bill, and that's what we'll be doing over the break," the spokesperson said.

MedPAC URGES RELEASE OF PART D DATA . . . begins on page one

income subsidy program, it told GAO that proprietary Part D information “may be used by officers, employees and contractors of the Department of Health and Human Services” but not by entities outside CMS, according to correspondence obtained by *Inside CMS*.

Meanwhile, the Medicare Payment Advisory Commission (MedPAC) issued a draft recommendation Nov. 8 that urges Congress to pass legislation which would mandate that CMS turn over the data to “congressional support agencies and selected executive branch agencies for purposes of program evaluation, public health and safety.”

MedPAC researchers explained during the meeting that while CMS proposed a data sharing rule last October, stakeholders may try to stop the rule on the grounds that it would allow the release of proprietary drug information and violate patient and provider privacy. There may even be a court challenge to the rule, a MedPAC researcher said.

The oversight and advisory roles that GAO and MedPAC perform, respectively, trump those concerns, researchers told MedPAC.

“The Commission needs drug claims to help us carry out our mandate of advising the Congress on Medicare policy,” said Rachel Schmidt, a MedPAC researcher. “In fact, I’ve heard many comments around the table this morning on how you think there are particular projects we should be undertaking in order to promote program evaluation here.”

Some of the questions MedPAC, and other researchers, could potentially answer with the claims data include:

- How many Part D enrollees are entering the coverage gap and whether the higher cost-sharing in the gap is affecting adherence to drug therapy.

- Do certain types of Part D benefit designs encourage appropriate use of drugs compared with others?

Key lawmakers have seesawed on the issue. As Senate Finance Committee Chair last year, Charles Grassley (R-IA) sponsored legislation (S. 3897, the Medicare Data Access and Research Act) that would have required CMS to provide the data to researchers who work for a variety of agencies under the umbrella of HHS, but also to congressional support agencies like GAO and the Congressional Budget Office (CBO).

Then-ranking Democrat Sen. Max Baucus (MT) co-sponsored the bill. However, when Grassley reintroduced the bill last May (S.1507, the Access to Medicare Data Act of 2007), along with current committee Chair Baucus, the language which would have required Medicare officials to hand over drug data to GAO and CBO was cut from the bill. Instead, only HHS agencies, like the FDA and the Agency for Healthcare Research and Quality (AHRQ), were named. HHS Secretary Michael Leavitt would have authority to release data, according to the legislation, but only to another “agency or center within” HHS.

An early version of last year’s “health extenders” bill (H.R. 6111, the Tax Relief and Health Care Act of 2006), included language requiring the data go to CBO and GAO, but that section of the bill (112) ended up on the cutting room floor.

CMS’ proposed rule would provide government agencies such as FDA, the National Institutes of Health and AHRQ, as well as researchers with the OIG, GAO and CBO, access to Part D data. External researchers based at universities or independent research institutions could also request the data.

As Stark points to report as evidence of potential savings...

HOUSE LAWMAKERS BLAST OIG REPORT ON WHEELCHAIR PRICING

In the wake of recent findings that CMS pays vastly more for power wheelchairs than suppliers charge on the Internet, at least two lawmakers have joined industry in decrying the findings for ignoring tangential costs related to the outfitting of Medicare beneficiaries.

Reps. Tom Allen (D-ME) and Ron Lewis (R-KY) said the findings dismiss “extensive service-related costs associated with Medicare compliance” that investigators should have considered — a sentiment they conveyed to their House colleagues in a Nov. 14 letter.

“While we do not argue that lower prices may be available to individuals who can pay cash and require little or no servicing, we find it inappropriate and misleading to compare those prices to the service delivery model for power wheelchairs under the Medicare program,” the lawmakers wrote.

Costs associated with assembly, delivery, on-site fittings, on-site trainings, claims processing and home assessment for Medicare wheelchair recipients all went unmentioned in the report, they added.

Issued last month by the HHS Office of Inspector

General (OIG), the report found that Medicare fee schedule rates for power wheelchairs were, on average, 45 percent higher than median prices found online for 24 of the 28 procedure codes surveyed. Had CMS adopted the Internet rates, OIG found, the savings to the agency and patients would have totaled about \$39 million in the first quarter of 2007 alone (see *Inside CMS*, Nov. 15).

In response to the report, Rep. Pete Stark (D-CA) sent a Dear Colleague letter of his own, drawing attention to the findings as evidence that potential Medicare savings exist in the power wheelchair arena.

“Based on this analysis, the OIG concludes that lower prices for wheelchairs — and savings — are available to consumers and the Medicare program,” Stark wrote in the Nov. 9 letter.

Industry stakeholders are concerned that lawmakers will use the report to validate wheelchair cuts as they work to finalize a year-end Medicare package the Senate Finance Committee is expected to mark up Dec. 5 (see related story).

In Nov. 12 letters to both OIG and Stark, the American Association for Homecare sounded off about “the serious

implications of this report on policymakers and the effect it may have on new legislative and/or regulatory initiatives.”

A spokesperson for The Scooter Store, a large Texas-based wheelchair supplier, claimed the OIG findings seem to promote a system in which power wheelchairs are “drop-shipped” to some of the most frail and vulnerable people in the country, who would then be responsible for assembling the equipment themselves.

LAWMAKERS LEAVE WASHINGTON WITHOUT SCHIP DEAL IN PLACE

A deal on a compromise package to reauthorize the State Children’s Health Insurance Program (SCHIP) has eluded House and Senate negotiators from both parties who exchanged written proposals in several late-night meetings before leaving town for the Thanksgiving recess.

Senate Majority Leader Harry Reid (D-NV) said Friday morning (Nov. 16) that he and House Speaker Nancy Pelosi (D-CA) had “bent over backwards” to try to accommodate House Republican hold-outs, but in the end they could count on only a handful of new GOP votes for the product that has emerged after weeks of tedious negotiations. Reid said their patience is “about at an end.”

“It’s really a shame that funding health care for kids is not going to happen. We’re going to go from what we wanted — about 10 million insured — to about four-and-a-half million. Really too bad,” he said.

Two days earlier House Republicans, according to Rep. Judy Biggert (R-IL), sent their “final offer” to the Senate’s SCHIP “Group of Four” — Sens. Max Baucus (D-MT), Chuck Grassley (R-IA), Jay Rockefeller (D-WV), Orrin Hatch (R-UT) — and House Energy & Commerce Chair John Dingell (D-MI). On Thursday, that coalition responded with their offer.

At 4 p.m. that day, two groups of lawmakers met separately in the Capitol in a bid to hash out a final deal. Senate Democratic and Republican staffers and House Democratic staffers occupied one side of the hall, and House Republican staffers on the other. Each side was mulling the other’s “final offer,” but not talking with one another.

Later that evening, Biggert was seen talking on the House floor with House Majority Leader Steny Hoyer (D-MD) and Democratic Caucus Chair Rahm Emanuel (IL), presumably about the negotiations, which eventually broke down as House members returned to their districts for the Thanksgiving recess.

Biggert, who wouldn’t talk about specific issues, said there remained differences on five or six major points.

“Some things we have given on and some things they have given on ... I think it’s a really good product; it’s just if we can get all the details and we can all agree. And there are some issues that we really need to work on,” she said last night.

Among the issues that the negotiators could not build consensus on, according to a House Republican staffer: poor kids first. The two sides apparently could not decide upon what level of children below 200 percent of poverty

Allen and Lewis are no strangers to the topic, having sponsored legislation earlier in the year to exempt high-end Group 3 power wheelchairs from CMS’ nascent competitive bidding program for durable medical equipment. Supporters of the bill say the “one-size-fits-all” approach of the program is unsuitable for complex equipment that often requires customization (see *Inside CMS*, Oct. 4).

states must cover before they expand coverage above 250 percent of the federal poverty level or a benchmark set by the 20th best state (at enrolling low-income children) and “whether or not that’s an actual, real standard,” the staffer said.

House Republicans continued to see language that they characterized as allowing “loopholes or escape hatches” that might allow the states to move children at higher income levels into Medicaid, the staffer said.

Section 115 of the recently passed SCHIP bill allows states to go above 300 percent of poverty in their Medicaid programs and “that remains a real concern” for House Republicans, the staffer said. The bill is the second iteration passed by Congress.

The provision, the GOP staffer said, “incentivizes states to grossly expand their Medicaid programs” and could lead to the gutting of the SCHIP block grant program in favor of the Medicaid entitlement program, the staffer said.

What House GOP negotiators have been arguing for is a hard cap at 300 percent of poverty for both the SCHIP and Medicaid programs.

“Why do we need a middle class entitlement for essentially healthy kids and healthy adults?” the staffer said.

Another sticking point: the “date of consequence” for states that don’t meet the “rigorous” standard that the White House has insisted upon regarding low-income coverage. Negotiators were weighing a four-year window before a state would face consequences for enrolling children above the 250 percent level without having enrolled 80 percent or 90 percent of SCHIP eligible kids living below 200 percent of poverty, the staffer said.

It’s unclear whether negotiators were able to resolve issues surrounding proof-of-citizenship documentation requirements or other sticking points that Rep. Joe Barton (D-TX) and others complained about in the second SCHIP bill. These included Section 114, which Barton argued would allow states to apply income disregards that would let higher-income families gain SCHIP coverage. Language in that section indicates that eligibility is capped at 300 percent of the poverty level, but makes an exception “for the application of a general exclusion of a block of income that is not determined by type of expense or type of income.”

A children’s advocate suggests that the blame for not getting the deal done must be divided among both parties, but that the lion’s share of it must be laid at the feet of

President Bush.

“The moment he found his veto pen under his desk, after seven years of wondering in the wilderness, trying to find his fiscal conservatism, he chose to veto legislation that would bring health care to the most needy kids in this country,” he said. “At that moment, he made this issue political.”

Then the advocate also criticized House lawmakers for

not reaching out in a bipartisan way at the beginning of the process.

“The point is, we are here now because the Democrats [messed] up the beginning.

“Now they may learn to lead, after being in the deep dungeons of the minority for 12 years — it may take some time. But what they have demonstrated is that they’re not very good at being in the majority.”

Quick Takes

OVER 200 STAKEHOLDERS MULL WAYS TO IMPROVE QUALITY OF CARE IN NURSING HOMES

Quality improvement organizations, nursing home associations, consumers and federal and state officials gathered this week in Texas to chart a course for quality improvement in nursing homes. The participants are part of a national campaign launched last year that monitors key indicators of nursing home care quality. Over 6,200 nursing homes have signed up for the campaign and have committed to work on a handful of quality improvement goals.

CMS PROPOSES RULE ON MEDICAID INTEGRITY AUDIT PROGRAM REQUIREMENTS

The proposed rule states that the eligible entity should demonstrate the capability to carry out the contractor activities; agree to cooperate with the Inspector General, the Attorney General and other law enforcement agencies as appropriate; and maintain an appropriate code of conduct. CMS calls for establishment of a Conflicts of Interest Review Board to help contracting officers resolve conflicts of interest.

BIDDERS’ CONFERENCE FOR MEDICARE CLINICAL LAB SERVICES COMPETITIVE BIDDING DEMO RESCHEDULED FOR DEC. 5

The bidders’ conference, originally scheduled for Oct. 31 in the San Diego-Carlsbad-San Marcos metropolitan statistical area, was postponed due to fire emergencies in California. The demonstration will use competitive acquisition for payment of clinical laboratory services that would otherwise be subject to regular Medicare Part B fee schedules.

HOUSE ENERGY & COMMERCE MEMBER FERGUSON WILL NOT SEEK REELECTION NEXT YEAR

Rep. Mike Ferguson (R-NJ) announced Nov. 19 that he will not seek reelection next year. Ferguson, a member of the Energy & Commerce health and oversight & investigations subcommittees, pushed to hike Medicare reimbursement for diagnostic laboratory tests, sponsored legislation allowing state pharmaceutical plans to wrap around the Medicare benefit, voted against letting HHS negotiate prices under Part D, and was one of five GOP members to vote for the House Children’s Health and Medicare Protection (CHAMP) Act.

AARP PRAISES CMS FOR PUBLISHING DATA ON POOR-PERFORMING NURSING HOMES

CMS’ new plan to publish data on poor-performing nursing homes as part of a Special Focus Facility program drew praise from AARP, which earlier this year urged the agency to release

such information. Last week, the seniors group called on Congress to improve nursing home quality by demanding transparency and documentation of nursing home ownership; better data on nursing home staffing levels; and enforcement of existing nursing home quality standards.

GRASSLEY ISSUES CATTLE CALL FOR WHISTLEBLOWERS

The Iowa Republican already known for sheltering industry and federal government whistleblowers is now publicly inviting those with information about drug company misdeeds to call his office or anonymously send documents by fax. Two weeks ago, Grassley even gave his office fax number during a Senate floor speech to make it easy: 202-228-2131.

SENATORS WEIGH AMENDING TAX LEVY LAW TO HELP RECOUP MEDICAID PROVIDERS’ BACK TAXES

A Senate committee urged CMS and IRS to collaborate — through the Treasury Department — after the Government Accountability Office found that 5 percent of Medicaid providers owe back taxes. CMS argues that the law prohibits disclosure of taxpayer data to CMS and states, and that Medicaid’s ability to serve low-income patients would be compromised if Medicaid providers were screened for back taxes. Lawmakers are considering whether Medicaid payments should be incorporated in the continuous levy program that allows the government to recoup certain federal payments made to delinquent taxpayers.

GREGG DISAPPOINTED HHS APPEALED COURT RULING REQUIRING RELEASE OF PHYSICIAN-IDENTIFIED CLAIMS DATA

Sen. Judd Gregg (R-NH), in a Nov. 7 letter to HHS Secretary Michael Leavitt, complains about HHS’ decision to appeal the court ruling and touts his own bill that would require CMS to share Medicare data with qualified private sector organizations.

NEW YORK, EMPIRE BLUE CROSS AGREE ON PHYSICIAN RANKING SYSTEM

Empire Blue Cross Blue Shield has agreed to improve its controversial doctor ratings program, inform providers and consumers about ranking criteria and update New York’s attorney general every six months. The deal between the insurer and state Attorney General Andrew Cuomo is supported by American Medical Association, Medical Society of the State of New York, Consumers Union and other advocacy groups. Cigna cut a similar deal with Cuomo in October over its physician rankings program. Doctors have claimed that rankings are error-prone.

FORMER FDA CHIEF COUNSEL'S BROTHER TAPPED AS DEPUTY HHS SECRETARY

FDA chief Andrew von Eschenbach says the appointment of Tevi Troy to deputy HHS secretary bodes well for FDA's Critical Path Initiative. Tevi Troy, who served as President Bush's deputy assistant for domestic policy for the past two years, also happens to be the younger brother of Dan Troy, who was FDA chief counsel from 2001 to 2004.

Tevi Troy's biography states that he will be involved in all HHS operations, which include food and drug safety. He also serves as an HHS regulatory policy officer, overseeing the development and approval of all HHS regulations and significant guidance. Among the initiatives that Troy directs are bioterrorism, the president's management agenda, and public health emergency preparedness.

Soon after his Senate confirmation, Tevi Troy visited FDA in the last week of August for three days, according to an e-mail from von Eschenbach to agency staff. Von Eschenbach stated that the significant time Troy spent at the agency so early in his tenure shows his strong support of FDA.

"I know Dr. Troy personally, having worked with him during his tenure at the White House, and we share a common vision of reshaping approaches to health care by relying on the rapid progress being made in biomedical research and emerging technologies," von Eschenbach writes.

"As we move forward with our various initiatives such as the critical path and creating a regulatory pathway for

advances in science and technology, I know he will be a great asset in his leadership role at the Department," the e-mail states.

FDA announced the Critical Path Initiative years ago but has had a difficult time funding it. Congress recently created the Reagan-Udall Foundation, which will house the initiative. Consumer and patient advocates recently have criticized the foundation as a way for industry to influence the drug development process because it is largely industry funded. Rep. Rosa DeLauro (D-CT), chair of the House appropriations subcommittee that oversees FDA's budget, also says she is worried about industry's influence on the foundation.

The goal of Critical Path is to speed scientific discovery during early research to marketed therapies. It is supposed to move science toward more personalized medicine, which is integral to drug safety. A key goal is to promote duplicative research among companies by creating shared research tools.

It is unclear what role Tevi Troy plays in the Critical Path initiative. HHS declined comment.

Troy's work in the administration began at the Department of Labor, where he was the deputy assistant secretary for policy and the director of the Office of Faith Based Initiatives. From 2003 to 2004 he was a special assistant to the president, deputy cabinet secretary and the White House liaison to the Jewish community. From 2005 to 2007, Troy served as a deputy assistant to President Bush for domestic policy.

NEW MEDSUN WEB SITE EXPANDS ACCESS TO DEVICE ADVERSE EVENT DATA

A new Web site for FDA's Medical Product Safety Network will make some medical device adverse event reports available to a broader audience of health care providers. Events reported to MedSun were previously available only to its roughly 350 member facilities.

By putting those reports online, FDA is giving non-members and the public access to potentially important information about medical devices.

"This is to make what we see public to the rest of the community," FDA patient safety officer Diana Kaufman said.

Users can search reports by manufacturer, device brand, device type, or type of event.

A search for Sprint Fidelis defibrillator leads, for example, yields two reports of improper shocks associated with the device. The leads have been recalled, and Congress is investigating how FDA approved the products.

The site also includes FDA newsletters and transcripts of audio conferences.

FDA's device center launched MedSun in 2002 and has been incrementally expanding it since then. The network collects adverse event reports from members using a standardized reporting procedure, which the agency hopes will ultimately lead to a large-scale improvement in the consistency and depth of adverse event reporting.

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CMS TO PUT WORST PERFORMING NURSING HOMES ON WEB SITE

CMS Acting Administrator Kerry Weems told Senate aging committee members earlier this month that the agency will soon post the names of the country's worst performing nursing homes on the agency's Web site. The initiative, one of several agency efforts to boost nursing home quality and transparency, quickly received kudos from the nations' largest seniors group.

"Residents in the poorest performing nursing homes and their families have a right to know that the care they receive may be sub-standard," AARP legislative counsel David Center said in a release. "Earlier this year, AARP called on CMS to release this information, and we are pleased CMS has agreed. People in need of 24-hour care should not have to be concerned that their nursing home is a potentially harmful environment."

Sens. Herb Kohl (D-WI) and Charles Grassley (R-IA) have included a similar measure in the Nursing Home Transparency and Improvement Act they plan to introduce in coming weeks. At the Nov. 15 hearing, Kohl praised Weems for focusing on transparency and said "shining the light" on the poor performing facilities should encourage those who want to stay in business to improve.

"It is in everybody's best interest to let consumer's know which nursing homes repeatedly demonstrate deficiencies and violate government standards," Kohl said. "These homes are obviously not doing their jobs."

The 62 worst performing facilities will be posted "on or before" Dec. 1, Weems said. He added that the information has been collected and is ready for publication, but the agency wanted to give facilities time to inform patients, workers and family members about the situation prior to acting. "We don't want to induce panic," he said.

The 62 facilities are on CMS' Special Focus Facility list. Nursing homes on the special focus list receive twice the number of surveys compared to others. If problems continue, CMS moves forward with "progressive enforcement," Weems said. Such enforcement measures continue until the problem nursing home either graduates from the Special Focus program due to significant improvements, is terminated from Medicare/Medicaid, or is given more time due to improvement. Other developments — such as sale to a new owner with a better track record — may also affect a nursing home's status.

Grassley, who made up the first of three witness panels at the aging committee hearing, pointed out in his testi-

mony that the vast majority of nursing homes provide quality care on a consistent basis. "But, as in many sectors — this industry is given a bad name by a few bad apples that spoil the barrel," the Iowa senator said.

CMS is able to sanction poor performing homes, but often they are able to "yo-yo" in and out of compliance. A GAO report issued earlier this year analyzed sanctions on 63 homes with a history of problems and found that 31 of them cycled in and out of compliance, including eight homes that did so seven times.

GAO criticized CMS for imposing weak civil monetary fines that consistently hovered on the low end of the penalty scale and pointed to significant lag times between when the penalty was imposed and when it was collected, which lessens the impact.

Weems said the agency plans to push for legislation by 2009 that will allow CMS to immediately collect fines and keep the money in escrow until the appeals process has run its course (see *Inside CMS*, May 14).

Weems also presented a chart outlining additional nursing home quality improvement goals for the upcoming year, including a value-based purchasing demonstration set to launch next spring, an April 2008 symposium on a patient-centered approach to care, and initiatives to

control infections, reduce pressure ulcers and improve fire safety.

Also, in response to a Sept. 23 *New York Times* story that indicated nursing home quality decreases when facilities are purchased by private equity groups, Weems said CMS is ready to unveil a system to track ownership of nursing homes and other facilities.

The Provider Enrollment Chain and Ownership System (PECOS) will allow CMS to maintain information on entities that own 5 percent or more of a nursing home and ensure that only eligible providers are enrolled in Medicare. Weems said staff are working on the databases, which is expected to be 70 percent populated by the second quarter of fiscal 2008.

Nursing home ownership and quality likewise was the focus of a Ways & Means health subcommittee hearing, also held on Nov. 15. Committee Chair Rep. Pete Stark (D-CA) said he and ranking GOP member Dave Camp (R-MI) would pursue a Government Accountability Office investigation into how ownership structure affects the quality of care.

"It is in everybody's best interest to let consumer's know which nursing homes repeatedly demonstrate deficiencies and violate government standards."
— Sen. Herb Kohl (D-WI)
