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Labs Pleased CMS Opening Process For Revising Medicare Pay Rates

Laboratories are pleased that CMS is opening the process of setting reimbursement for laboratory services, just as it is doing for physician services, which will give labs more say over pay rates. The change, which is part of the annual Physician Fee Schedule rule unveiled late last week, adds to the run of positive developments for labs that started when Congress replaced CMS' plan to change clinical lab fees based on technological changes in the patch to the Sustainable Growth Rate formula earlier this year.

CMS adopted the lab industry's recommendation that the agency use notice and comment rulemaking to revise Medicare pay for lab services, instead of listing revised pay rates in a final payment rule when it's too late for labs to comment on the changes. However, the law still lets CMS cut pay rates by as much as 75 percent by 2022, although that would require CMS to cut pay the maximum amount in each of six years starting in 2017.

Labs were caught off guard this time last year when CMS proposed cutting pay for lab tests 25 percent by capping Medicare pay to independent labs at the lower rates paid to hospital outpatient or ambulatory surgery centers. That steep pay cut was the result of a CMS plan to adjust pay based on changes in technology. At the time, then-CMS Principal Deputy Administrator Jonathan Blum said

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CMS Proposes Pay Rate For Primary-Care Code; Hikes Doctors Influence Over Pay Rates

CMS on Thursday (July 3) proposed a physician pay rule that adds important details to the new, primary-physician-backed pay code for managing patients and that gives physicians more influence starting in 2016 over Medicare pay rates. Primary physicians are not paid for many services they provide, said Reid Blackwelder, president of the American Academy of Family Physicians, so CMS last year established a code that pays primary care physicians for managing beneficiaries with at least two chronic conditions.

"Chronic care management services include regular development and revision of a plan of care, communication with other treating health professionals, and medication management," CMS stated.

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Enrollment In Duals Demos Doubled July 1, Mostly Due To Auto-Enrollment

On July 1, enrollment doubled to about 120,000 dually eligible beneficiaries in the so-called duals demonstrations run in five states, and the vast majority of that increase is due to beneficiaries being automatically, or "passively," enrolled, according to a CMS official. Beneficiary advocates dislike passive enrollment, and the National Senior Citizens Law Center last month asked CMS and California officials to suspend passive enrollment in that state's demo because of the "sheer number of problems."

The enrollment spike is due to factors in five states coming together at once, a CMS official said. California accounted for a big chunk of it. The state has been phasing in passive enrollment by county since April, and enrollment

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OMHA Mediation Pilot Puts CMS, Providers Together To Resolve Appeals

Some stakeholders are skeptical that the Office of Medicare Hearings and Appeals' recently proposed settlement and mediation pilot will help relieve the backlog at the third level of the Medicare appeals system, but others say the pilot is worth a shot, though outstanding questions remain. Under the pilot, OMHA will facilitate deals between CMS and certain providers or suppliers

OMHA recently released details on the settlement conference facilitation pilot, an alternate dispute resolution process in which OMHA will bring CMS and providers together "to discuss the mutually agreeable resolution to the claims appealed to an Administrative Law Judge hearing." If CMS and providers are able to agree on a deal to resolve disputed claim denials, the

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LTCHs, IRFs To Push Sector-Specific Quality Reviews In Talks With CMS

CMS will conduct voluntary interviews with long-term care hospitals and inpatient rehabilitation facility providers during July and August to get input on concerns those entities have with the Quality Review Program required by the Affordable Care Act — and industry officials plan to use the opportunity to push for sector-specific quality measures. Representatives from both the American Hospital Association (AHA) and the American Medical Rehabilitation Providers Association (AMRPA), which represent LTCHs and IRFs respectively, said they would like to see the quality reviews reflect issues, such as procedures and outcomes, specific to their facilities and the care they provide.

Currently the criteria currently used in quality reviews are the same for hospitals, nursing homes, LTCHs and IRFs.

AMRPA chairman Bruce Gans pointed out that IRFs provide very different care than traditional hospitals or LTCHs. For example, in a June 27 letter to CMS, Gans said that IRFs rarely treat antibiotic-resistant infections, unlike hospitals and nursing homes.

"It doesn't make sense to be measuring the same things across the spectrum, because different hospital systems are designed to accomplish different things," Gans told *Inside Health Policy*.

He said it would be more relevant IRFs to report on the progress of rehabilitation following knee-replacement surgeries and how long those gains are sustained after patients leave inpatient rehabilitation facilities.

"This is mission critical," Gans said. "This is really important stuff, and you want to make sure you got it right."

Akin Demehin, AHA senior associate director of policy, echoed Gans concerns. Although Demehin did not detail quality measures that AHA prefers, AHA would like to see "more measure development tailored to LTCHs" as opposed to being lumped in with regular hospitals and nursing homes.

"We see measure gaps and would like to see measures added that we think are appropriate for LTCHs," Demehin said.

Gans and Demehin both said CMS' calls for input show the agency is taking the quality review process seriously. They believe CMS will take suggestions from providers into account as they more fully develop quality review policies, rather than input from groups like the AHA and AMRPA becoming an exercise in bureaucratic futility.

Demehin pointed out that this was the second time care providers have been asked for input since the Quality Review program began in 2012.

"We're very pleased they're doing this again; to us it reveals they are taking our input seriously," he said.

In a background email to *Inside Health Policy*, CMS stated that it received positive responses from providers in regards to the earlier call for input referenced by Demehin, and that the agency has found it to be a useful evaluation tool.

Gans said while no group gets everything it wants, there is "a legitimate back and forth," between CMS and providers with regards to the Quality Review program.

"We share the objective of providing quality care, the only difference is on the details," Gans said. "They understand that people working in the agencies are very, very distant from the bedside. This process helps them understand the difficulties for the providers with boots on the ground."

In its background email, CMS said it will use the information from providers "to help direct future actions of the QRP."

"CMS plans to use the input to understand early trends in outcomes, to make adjustments as needed to enhance the

effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the quality reporting program is useful and meaningful to the providers," the email reads.

The phone and email interviews with providers who choose to participate will be conducted by Health Care Innovation Services, and reports or summaries of the interviews will not contain specific information on the providers who take part, according to CMS.

The interviews are designed to "assist CMS in better understanding the strengths, weaknesses, priorities and burdens associated with the QRP," according to notices from CMS asking for input. — *Todd Allen Wilson*

Lawmakers Ask OIG To Probe DME Bidding Before Program Expands

A bipartisan group of House lawmakers plans to ask the HHS Office of Inspector General to evaluate how the durable medical equipment bidding program is affecting beneficiaries' health, including looking at the enforcement of winning bidders' obligations and the way CMS comes up with a price for DME under the program. The lawmakers' planned letter also asks the OIG to explore the potential of running an appeals office to handle stakeholder concerns.

The letter, signed by almost 40 representatives as of Tuesday (July 8) and supported by 38 organizations including the Advanced Medical Technology Association and the American Association for Homecare, is expected to go to the OIG next week. Reps. Tom Price (R-GA), Bruce Braley (D-IA), Tom Reed (R-NY), and Tammy Duckworth (D-IL) are continuing to ask colleagues to join them on the letter, saying that "critically missing from CMS is an independent evaluation of the program's impact on beneficiary health," and a full review of the program is necessary before the program expands nationally in 2016. A group of senators in May asked CMS not to expand the program until the OIG finishes examining the second round of bids.

"It would be a grave error if the bidding structure developed by the Centers for Medicare & Medicaid Services (CMS) severely reduces access to home support services just as Congress seeks to enhance care quality through greater coordination of care, especially for patients with complex and multiple chronic conditions," the House lawmakers' draft letter to the OIG says.

The lawmakers ask OIG to examine how the program works in practice, and one DME lobbyist says the lawmakers' detailed questions send a message that more specific information — and not grand statements from CMS — are important to measure the effects of the program and determine whether it's working.

"In sum, while we believe competitive bidding can reduce costs while maintaining beneficiary access to quality care, this hybrid program appears to be compromising seniors' health by reducing beneficiaries access to the supportive technologies and care that enables them to maintain their independence," the lawmakers' letter says.

When the second round of the program was ramping up, then-CMS Principal Deputy Administrator Jon Blum said the agency had virtually no complaints from beneficiaries about the program. But the lawmakers point out that the Government Accountability Office previously said CMS' methods for tracking the impact of the bidding program on beneficiaries were inadequate. The lawmakers also note that GAO did not independently evaluate the program's impact on beneficiary health, although a recent GAO report and an OIG report found few beneficiary problems with the bidding program.

Among other concerns, the lawmakers ask the OIG to look into why beneficiaries who were receiving DME prior to the bidding program are no longer doing so. It's important to know if they no longer need the DME, started paying for it themselves, went without supplies, moved to a nursing home, are getting supplies from the emergency room or have passed away, the lawmakers say. The OIG should also look into how much beneficiaries spend on their health both inside and outside of the bidding areas.

"CMS has testified that they track only beneficiaries with current claims (within the last 120 days) — that is, the people who are getting their prescriptions filled. The health impact on all seniors is the right measure of the program," the letter says.

The lawmakers also ask the OIG to looking into whether the winning bidders are fulfilling their contracts.

"This information is crucial because if suppliers don't provide products and services as required by their contracts, then seniors' access to the products prescribed by their physicians is compromised," the letter says, especially for the more expensive products. The lawmakers say not making sure all products in a certain DME category are available to Medicare beneficiaries is a breach of contract, but CMS is not enforcing the requirement and beneficiaries do not necessarily have access to all types of DME.

Beneficiary advocates at the Center for Medicare Advocacy also are looking into whether suppliers are failing to fulfill their contracts by not providing delivery as required on certain items, and there is concern that the winning bidders are compromising beneficiaries' ability to get their necessary DME.

The lawmakers also are asking how CMS decided suppliers could grow their businesses — in some cases exponentially — in a short period of time, and how the future capacity of a supplier was determined. The OIG also should look into whether suppliers were able to start supplying all of the products they were responsible for on the first day of their

contract, and if the suppliers continue still are able to do so, the letter says.

The OIG should look into concerns about the number of suppliers and their capacity to provide DME, including how many suppliers have left the bidding program, why they left, and any actions taken to replace those suppliers, as well, the letter says.

The lawmakers point to concerns with licensure in the second round of bidding in the "Dear Colleague" letter, and also ask the OIG to verify if winning suppliers were licensed and certified. Other groups of lawmakers previously asked the OIG to look into the licensure issue, to see if contracts were awarded to unlicensed suppliers in certain states in order to hit a predetermined price for DME. The OIG said it would examine the second round of the program in Tennessee, Maryland, Michigan and Ohio.

"Without the information requested above, Members of Congress cannot responsibly assure the well-being of the seniors they represent or the sustainability of this extremely important program designed to support the quality care of Medicare beneficiaries in their homes effectively," the draft letter to the OIG says. — *Michelle M. Stein*

HRSA Makes Changes to 340B Audits; Safety Net Hospitals Concerned

The Health Resources and Services Administration posted changes to its 340B drug pricing compliance audit process Thursday (July 3), saying audited entities will have to wait until the agency's final report is issued on an audit before it can be appealed. While the changes will shorten the audit process, they may have unintended consequences that are harmful to both the entities being audited and HRSA, which could open itself to lawsuits, a source that represents organizations that participate in the 340B program said.

Previously 340B entities that receive reduced pricing on certain prescription drugs were allowed to appeal the findings of an audit after they received a preliminary report from HRSA.

In the announcement posted on HRSA website the agency says the changes were designed to make the compliance audit process "more efficient and effective."

Under the new process audited entities will have 30 days following the issuance of a final audit report to appeal the HRSA's findings, and they will have 60 days to submit a corrective action plan.

The 340B discount drug program was authorized by Congress in 1992 to offer lower prices for prescription drugs to hospitals that serve a disproportionally high number of low-income and uninsured or underinsured patients. The program allows certain federally qualified health centers and other entities to receive the same drug discounts mandated by the state Medicaid program. Under the Affordable Care Act the program was expanded to include some outpatient clinics.

Since the expansion of the program under the ACA it has come under congressional scrutiny to ensure that hospitals and clinics are not abusing the process.

In its update of the audit process, HRSA said it plans to increase the number of audits it conducts in fiscal year 2015.

An HRSA official reiterated the basics of the changes to the process posted on the agency's website, in an email to *Inside Health Policy* Thursday following a request for information.

Maureen Testoni, general counsel for Safety Net Hospitals for Pharmaceutical Access, the group that represents organizations that participate in the 340B program, said she thinks the changes were made to make the audit process conclude more quickly. She said many organizations that take part in the program had complained that the audit process took too long from start to finish.

She said, however, that the changes could cause problems for both the hospitals and clinics that are audited and HRSA. The shortening of the process takes away the "basic due process" for audited entities to make sure they understand the reasons and issues HRSA is dinging them on, she said.

The shortened process could open HRSA to lawsuits brought by audited entities that feel the agency did not understand the technical points they were making in their appeals, she said.

"Shortening the process reduces the understanding of complex, fact-based issues," Testoni said. "It could have a significant impact on the reliability of the audit results." — *Todd Allen Wilson*

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CMS Moves On Bundled Primary Procedure Pay

CMS is moving ahead with a plan, put on hold last year, to shift hospital outpatient payments from the current hybrid approach to a prospective payment system that bundles payments for certain primary procedures, the agency revealed in a proposed 2015 OPPS rule unveiled late Thursday (July 3). The agency laid out the new payment policy in the 2014 OPPS final rule but delayed its implementation to give stakeholders time to grapple with the shift. CMS' newly proposed rule made some adjustments to the policy, which entails a single payment for all related or adjunctive hospital services provided to a patient during certain primary procedures, such as the insertion of a pacemaker.

The 2015 hospital OPPS and Ambulatory Surgical Center (ASC) payment rule also proposes to:

• Update and streamline programs that encourage high-quality care in outpatient settings.

• Provide a 2.1 percent OPPS market basket increase for 2015 based on the projected hospital market basket increase of 2.7 percent minus both a 0.4 percentage point adjustment for multi-factor productivity and a 0.2 percent adjustment required by law.

• Begin collection of data on services furnished in off-campus provider-based departments beginning in 2015 by requiring hospitals and physicians to report a modifier for those services furnished in an off-campus provider-based department on both hospital and physician claims.

• Continue average sales price (ASP) + 6 percent payments for non-pass-through drugs and biologics payed separately under the OPPS.

Most significantly, the proposed rule — which affects more than 4,000 hospitals, including general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals and cancer hospitals — cements the agency's plan to shift to the new comprehensive-Ambulatory Payment Classification (APC) group policy. Under the policy, categories of related items and services will be packaged into a single payment for a comprehensive primary service. The shift makes the OPPS more consistent with a prospective payment system, moving away from the current hybrid of a prospective payment and fee schedule.

In the 2014 payment rule, CMS created 29 comprehensive-APCs but delayed their implementation to give the agency and hospitals time to evaluate the payment shift.

The 2015 proposed rule suggests adding several comprehensive-APCs, including some lower-cost device-dependent APCs not proposed last year and two new APCs for other procedures and technologies that are either largely device dependent or represent single session services with multiple components. But CMS also proposes to restructure and consolidate some of the current device-dependent APCs with similar costs based on 2013 claims data.

As a result, CMS now proposes a total of 28 comprehensive-APCs for 2015 versus the 29 comprehensive-APCs listed in the 2014 final rule.

The newly proposed rule also includes new policies for ancillary services. Under OPPS, CMS currently pays separately for services that are ancillary, or are integral, supportive, dependent, or adjunctive to a primary service. These ancillary services are primarily minor diagnostic tests, but therapeutic services can also be ancillary services.

For 2015, CMS proposes conditional packaging of all ancillary services assigned to APCs with a geometric mean cost of $100 or less (prior to applying the conditional packaging status indicator to the services within these APCs), as a criterion to establish an initial set of conditionally packaged ancillary service APCs. In cases in which these ancillary services are furnished by themselves, CMS proposes to make separate payment for the services only.

"Exceptions to the ancillary services packaging policy include preventive services, psychiatry-related services, and drug administration services," a CMS fact sheet states. "Psychotherapy and related services are excepted because these services are similar to visits and drug administration is excepted because we are considering alternatives for drug administration services including the associated add-on codes."

CMS also proposes that for a hospital to receive an outlier payment under the OPPS, the cost of a service must exceed the multiple threshold of 1.75 times the APC payment rate and exceed the 2015 fixed dollar threshold of the APC payment plus $3,100. The agency estimates these thresholds would pay at the proposed target of 1 percent of total OPPS spending in outlier payments.

Also, the rule would continue setting the community mental health center outlier threshold at 3.40 times the highest CMHC Partial Hospitalization Program (PHP) APC payment rate (that is, APC 0173 (Level II Partial Hospitalization)) for 2015.

Under the rule, ASC payments for 2015 are projected to have a 1.7 percent Consumer Price Index for all urban consumers. The multifactor productivity adjustment is projected to be 0.5 percent, resulting in an MFP-adjusted CPI-U update of 1.2 percent for 2015.

CMS also proposes to update payment rates for community mental health centers and hospital-based partial-hospitalization programs. For community mental health centers, the proposed 2015 APC geometric mean per day cost for Level I (three services) would be $97.43 and for Level II (four or more services), $114.93. For hospital-based PHPs, the

proposed update to the APC geometric mean per day cost would be $177.32 for Level I and $190.21 for Level II.

The agency also proposes some policy changes, including a new process to recover overpayments that result from the submission of erroneous payment data by Medicare Advantage organizations or Part D plan sponsors in limited circumstances in which plans fail to correct those data after being requested to do so by CMS. Plus, the agency lays out an appeals process for MA and Part D sponsors to challenge CMS' decisions that payment data are erroneous.

"The appeals process would have three levels of review that would include reconsideration, an informal hearing, and an Administrator review," CMS' fact sheet says.

The agency also proposes to revise the requirements for physician certification of hospital inpatient services. CMS currently requires a physician certification, including an admission order and certain additional elements, for all inpatient admissions. According to the fact sheet, "CMS found that for shorter stays and non-outlier stays, the admission order is a sufficient safeguard from both a beneficiary and Trust Fund protection standpoint." As a result, the agency proposes the admission order continue to be required for all admissions, but the physician certification only be required for outlier cases and long-stay cases of 20 days or more.

The proposed rule also lays out quality program changes.

CMS proposes to remove three measures — a cardiac care measure (OP-4: Aspirin at Arrival (NQF #0286)) and two prophylactic antibiotic surgery measures (OP-6: Timing of Prophylaxis Antibiotics and OP-7: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)) as performance is high with little variation between hospitals. CMS is proposing the addition of one claims-based measure (OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy) for the 2017 payment determination and subsequent years. CMS also proposes to change one chart-abstracted measure (OP-31: Cataracts — Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)) from required to voluntary reporting.

CMS also proposes modifications to the Hospital outpatient quality review program validation process and formalization of a review and corrections period.

CMS will accept comments on the proposed rule until Sept. 2 and hopes to issue a final rule on or around Nov. 1, the fact sheet says. — *Donna Haseley*

CMS Proposes Dialysis Pay Rule With DME-Pay Policies

CMS proposed increasing pay rates for dialysis facilities by 0.3 percent on average in 2015, cutting equipment reimbursement in non-competitive bidding areas to bring it in line with prices paid in the durable medical equipment bidding program and adding performance measures to the quality incentive program.

CMS released the end-stage renal disease (ESRD) proposed pay rule Tuesday evening (July 2). The agency projects that the proposed reimbursement changes would increase reimbursement for hospital-based facilities by 0.5 percent and would increase pay for freestanding facilities by 0.3 percent. Urban facilities would get an estimated 0.4 percent pay bump, and the pay rule would cut pay to rural facilities 0.5 percent.

Obamacare directed CMS to conduct more bidding for durable medical equipment. The rule proposes methodologies for using information from the bid program to adjust the fee schedule amounts for medical equipment in areas that the bid program is not in place.

These adjustments would reduce payments by more than $7 billion for the 5-year period of 2016 through 2020, according to an analysis by the consultant group Applied Policy.

CMS made three proposals for adjusting pay based on the bid program. The first regional adjustment proposal would apply to most situations, according to Applied Policy. That approach calls for adjusting fee schedule amounts for states in different regions of the country based on bid prices from competitions in those regions. The regional prices would be limited by a national ceiling of 110 percent of the average of regional prices and a floor of 90 percent of the average of regional prices.

The second approach would use a national ceiling as the adjusted fee for rural and frontier states. The third approach calls for adjusting fees for non-contiguous areas based on the average of bid prices from these areas or the national ceiling, whichever is higher.

CMS also proposed changes to the quality incentive program, which cuts pay by up to 2 percent to facilities that do not hit performance targets.

For 2017, CMS proposed eight clinical measures and three reporting measures that encompass anemia management, dialysis adequacy, vascular access type, patient experience, infections, hospital readmissions, and mineral metabolism management.

For 2018, CMS proposed a measure set that would contain 11 clinical measures and five reporting measures that include anemia management, dialysis adequacy, vascular access type, patient experience of care, infections, mineral metabolism management, safety, pain management, depression management, and hospital readmissions.

"This represents an evolution of the program that encompasses quality-of-care issues," CMS states.—*John Wilkerson*

Obama's Economic Advisers Detail Downside Of Not Expanding Medicaid

President Barack Obama's Council of Economic Advisers pointed out that the 24 states that have not expanded Medicaid eligibility under the Affordable Care Act are missing out on billions of dollars in federal funds, economic expansion and better health care outcomes for their residents in a report released Wednesday (July 2). Advocacy groups in favor of Medicaid expansion tout the report as a wake-up call for governors who oppose the program, with one group, Americans United for Change saying it will email copies of the report to Republican governors who are balking at expansion.

But a Medicaid source says the report is little more than finger-wagging on the part of the Obama administration, and it is unlikely it will bring opponents to the table.

The report, "Missed Opportunities: The consequences of state decisions not to expand Medicaid," contends that 5.7 million people will go without medical coverage in the 24 states that have not expanded their Medicaid eligibility to essentially 138 percent of the federal poverty level, which would be $16,105 a year for a single adult and $32,913 for a family of four. The District of Columbia and 26 states have expanded Medicaid under the ACA.

The states that have not expanded Medicaid will miss out on roughly $88 billion in federal funds through 2016, the report says. Under the ACA the federal government will cover 100 percent of the costs of the Medicaid expansion through 2016. Thereafter federal support of the program will decrease in steps down to a floor of 90 percent funding in 2020.

In addition to the loss of federal funding, the report says that these states, most of which have Republican governors and/or Republican controlled legislatures, will also lose out on hundreds of thousands of jobs created as a result of Medicaid expansion and increased economic activity to the tune of $66.4 billion from 2014 through 2017.

The additional economic activity comes from a number of factors, including expanded employment, health care providers seeing greatly reduced rates of providing unreimbursed medical care, and more financial stability for low-income families and individuals who gain coverage through Medicaid, according to the report.

"This evidence is clear that the consequences of states' decisions are far-reaching, with implications for the health and well-being of their citizens, their economies, and the economy of the nation as a whole," the CEA concludes in the report.

Low-income individuals and families who would gain health care coverage should their states expand Medicaid eligibility would see both better health care outcomes and financial stability, according to the report.

The report contends that quality of health for people who would gain coverage would increase because of their ability for regular doctor visits and preventative care. Mental health for these people would also be improved because of less rates of depression caused by the stress of not having access to quality health care and the financial havoc caused by the need for emergency care services, according to the report.

The CEA extrapolated this data using a scientific study of an earlier 2008 Medicaid expansion in Oregon, where slots in the program were assigned by a lottery due to a lack of funding to cover all of the Oregonians eligible for the program. The report's authors do add the caveat that their estimates may not track perfectly with the Oregon study because "the effects of past policy changes may not be a perfect guide to the effects of future policy changes."

While polling done by the Henry J. Kaiser Family Foundation routinely shows that the ACA as a whole remains unpopular with the American public — a June poll showed 45 percent of respondents held an unfavorable view of the ACA compared with 39 percent held a favorable view — a March poll showed 74 percent of respondents approved of the Medicaid expansion.

A handful of states that haven't expanded Medicaid coverage under the ACA — including Indiana, Pennsylvania, and Utah — are seeking waivers from the federal government to receive expansion funds to put forth their own plans to expand health care coverage in their individual states. Oklahoma received an extension of its federal waiver this week for a program for employer-sponsored health care for low-income individuals. Michigan and Iowa recently got similar waivers from the federal government.

These waiver attempts are based on the Arkansas model that used federal expansion funds to funnel low-income residents of the state into the private health care exchanges rather than traditional Medicaid.

Matt Salo, executive director of the National Association of Medicaid Directors, said the information detailed in the CEA report is not new information, but a case of "finger-wagging" at states that have not expanded coverage, by reiterating benefits they may be missing out on.

He said in some ways the CEA report misses the point of the argument.

"It's not about whether or not to expand Medicaid programs, but what is the best way to get coverage for states' low-income populations," he said. "Arkansas found a third way."

John Gorman, chairman of the Gorman Health Group, which advises insurers about various government programs, said the report is unlikely to sway leaders of the states that are holding out on Medicaid expansion.

Gorman said governors opposed to expansion are more likely to come around when hospitals in the their states begin complaining of heavy financial losses because they are no longer getting reimbursed for uninsured care. Under the ACA

hospitals no longer get reimbursement from the federal government for treating uninsured patients gratis. Gorman said because of this hospitals will also have a hard time issuing bonds, because financial institutions fear the bonds will go to pay to make up for the loss of reimbursement, rather, than "brick and mortar' expansions.

"Red state governors will start listening when hospitals come to them saying, 'You're killing us by not expanding Medicaid,'" Gorman said. "And I don't think they'll start listening until after the midterm elections."

Hospital advocacy groups like America's Essential Hospitals also chimed in Wednesday.

"It is imperative that financial support for essential hospitals is maintained so they can continue to care for these vulnerable populations and fill the other vital parts of their mission: to train the next generation of clinicians; deliver comprehensive, coordinated care to communities; provide specialized, lifesaving services, such as trauma and neonatal intensive care; and advance public and population health," said Bruce Siegel, president and CEO of America's Essential Hospitals.

Virginia, another state that has not expanded Medicaid, continues to see a stand-off on the issue between the Republican-controlled legislature and Democratic Gov. Terry McAuliffe. On June 20, McAuliffe vetoed a provision in the state budget that would have blocked Medicaid expansion in the state. He has promised to move forward with expansion through executive action, but has yet to reveal the details of his plan. — *Todd Allen Wilson*

CMS Adds 27 Innovation Awardees To Program's Second Round

CMS unveiled the second round of health care innovation awards Wednesday (July 9), increasing funding for both rounds of grants to up to $360 million for awards focusing on four areas that include reducing costs for hospital outpatients and testing improvements for certain providers. Unlike the first round of innovation awards, HHS looked for specific innovations in four areas for the second round: quickly reducing costs for patients in outpatient and post-acute settings, improving care for those with specialized needs, testing improved financial and clinical models for specific provider types, and linking clinical care delivery to preventive and population health.

Five of those in the second round of the innovation awards will focus on improving emergency care, while 10 others will look at improving care for children. Four others will focus on prevention and management of cardiovascular disease. Other awards will focus on promoting rural care coordination and telehealth (seven awards), improving care for elderly patients and providing support for aging in the community (seven awards), and better care for people living with HIV/AIDS.

The grantees will test these models across 27 states and Washington, DC. During the first round of the initiatives, 107 organizations across all 50 states received awards.

The 39 prospective awardees in round two will receive anywhere from $2 million to $23.8 million from Affordable Care Act funding over a three-year period. The awards will be made final later this summer, and each project will be monitored for measurable quality improvements and savings.

The agency released the first 12 prospective round two awardees which received as much as $110 million earlier this year, and CMS says in a fact sheet the second group of awardees "round out the anticipated recipients for round two of the Health Care Innovation Awards program."

"Over the last three years, we have embarked on an historic effort to improve the delivery of healthcare by testing new models of paying for quality care; and these awards will help spur private and public sector innovation in this endeavor," CMS Administrator Marilyn Tavenner said in a statement. — *Michelle M. Stein*

As troubled exchanges prepare for 2015 enrollment...

New Mexico Faces July 31 Deadline On Its Exchange As CMS Ups Pressure

CMS is upping pressure on states that want to fully operate their exchanges for 2015 open enrollment and New Mexico has a July 31 "go or no-go date" at which point the agency will make a decision, the chair of the New Mexico exchange board tells *Inside Health Policy,* who adds that it's becoming less likely the state will successfully transition to a completely state-run marketplace.

The July 31 date that has been agreed to by New Mexico and CMS comes as the agency continues discussions with states that are deviating from the "blueprints" HHS had approved for the first enrollment period, and as the final tally of state-based exchanges for 2015 remains in flux.

New Mexico is overseeing the SHOP exchange but had to rely on federal systems for the individual exchange, JR Damron, the chair of the New Mexico exchange board, says. HHS in 2013 had given New Mexico conditional approval to completely operate its marketplace for the first year it was live, but the state had to change course because it ran out of time to put all the technology in place. Idaho faced a similar situation and is also seeking to shed its "supported" state-based marketplace status for the next open enrollment period that starts in November.

Several of the state-based exchanges — including Maryland, Minnesota, Nevada, Oregon and Massachusetts — grappled with systems problems last year that resulted in fewer enrollees. Although a July 31 date has been put in place for New Mexico, sources believe there is no across-the-board deadline for when CMS will make decisions, though key evaluations and tests are taking place this summer for several states. Idaho and New Mexico are clearly in different positions than Massachusetts and Maryland, one source says, because the former two already have linkages to the federal exchange system.

Damron said CMS is tightening up its criteria for what states must do to transition to a state-based marketplace for 2015, because officials want to make sure that enrollment is successful the second time around.

As the July 31 date gets closer, Damron said he is less confident that New Mexico will be able to do the full transition and not have to rely on federal infrastructure for its individual exchange. CMS would not independently confirm the July 31 date.

Damron says the New Mexico exchange is holding a special board meeting on Friday (July 11) to discuss its readiness for 2015, based on whether its main vendor, GetInsured, will have the IT capabilities to get everything done by the state's Oct. 1 deadline. Damron suggested that potential issues with income verification are creating challenges for the state.

State-based exchange officials met with CMS staff in DC last month to discuss key metrics and issues for 2015. All state-based exchanges were invited to the meeting, a spokesperson for Idaho's exchange previously told *Inside Health Policy*.

One consultant familiar with the meeting said CMS is being much stricter with benchmarks this year, and that there is a stronger sense that agency cannot let states fail with enrollment in year two.

The source adds Idaho still believes it's on track to completely operate its marketplace. The spokesperson for Idaho would not say when CMS will make a decision about that state's ability to be a full state-based exchange for 2015 open enrollment, or if it would still need to rely on federal technology. The spokesperson said they are in communication with CMS almost daily to make sure the Idaho exchange is on track and all of its efforts are focused on becoming a fully-functioning state-based exchange for the upcoming open enrollment period.

Sources say Nevada and Oregon are sure to switch to the federally facilitated exchange for next year, as both exchange boards have voted to move in that direction. Massachusetts, another troubled state-based exchange that is simultaneously trying to fix its marketplace while preparing to link up to the FFE if it's necessary, could still tip either way, one consultant believes. Maryland is still seeking to quickly install software that was developed for Connecticut for the next open enrollment period, and recently set out a timetable for its board of directors. The consultant thinks Maryland is pretty committed to making the Connecticut software work and that state officials would resist using the FFE.

Massachusetts was set to have a key evaluation this month with CMS and state leaders, and a spokesperson for the Massachusetts exchange says staff will detail its progress and update the board on next steps at a meeting Thursday (July 10).

Last month, Massachusetts exchange staff indicated that the exchange will continue on the dual track if CMS officials are comfortable with software vendor hCentive's ability to fix the state-based exchange. Otherwise, the exchange will focus on switching to healthcare.gov for the next open enrollment period.

Some of the criteria Massachusetts lists for the early July checkpoint include governance structure, project management documentation, technical documentation, demonstration of required functionality, vendor contracts and project budget and approved financing. Massachusetts wrote at the time that most of the tasks were "in progress," though some were near final and one — establishing a single point of accountability via its governance structure —

was complete.

A spokesperson for the Maryland exchange would only say its review process with CMS is "going fine."

One consultant suggests that while Maryland will likely be ready to facilitate new enrollees by November, the source is skeptical that the exchange will be able to process renewals. In Maryland, 72,307 individuals enrolled in a qualified health plan as of May 31.

According to staff materials from a June 24 Maryland exchange board meeting, on June 23 the exchange went through a design "gateway review" with CMS. An operational readiness review is supposed to take place on Sept. 1.

— Rachana Dixit Pradhan

CMS Still Eyes Hospital Cost Data For Lab Pay . . . begins on page one

Medicare was overpaying for diagnostics, especially point-of-care tests, because CMS wasn't factoring in technological changes that have brought down the cost of the tests.

Many lawmakers sided with industry. They pressured CMS to back off those pay cuts, and the agency dropped them in the final version of the regulation. However, that final rule retained the proposal to account for technological changes when revising pay for codes in future annual pay rules. CMS kept the criteria vague, which industry and investors assumed was to make it easier to justify deep pay cuts in the pay rule that CMS just proposed for next year.

But then Congress prohibited CMS from revising pay rates based on technological changes. Congress did so in the legislation that patched the Sustainable Growth Rate formula to avoid schedule pay cuts to doctors, and it counted that change in lab-pay policy as an offset to the SGR-patch bill because the bill also cut lab pay rates, even though many believe CMS would have cut pay even further had Congress not stepped in. (Stock prices for the two primary labs, Quest Diagnostics' and Laboratory Corp., shot up the day that the House voted on the SGR patch.)

Traces of CMS' original plan are in the proposed rule that CMS released last week. The plan had been to cap Medicare reimbursement for independent laboratories at Outpatient Prospective Payment System (OPPS) rates. The OPPS rates are based on hospital cost reports, and last week's proposed rule states that CMS believes there are "various possibilities for leveraging available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated." Thus, CMS is still interested in using hospital data, even though the OPPS rates are not believed to be accurate for non-facility reimbursement, according to Julie Khani, senior vice president of the American Clinical Laboratory Association.

Khani said she is pleased with regulation, based on an initial read, and she stressed that ACLA staff are still working with CMS on implementing the changes from the SGR-patch bill. ACLA will submit comments to CMS on Monday at an event at which the agency is meeting with industry to discuss the changes. She expects the agency to implement the changes in a regulation separate from the annual lab fee schedule regulation.

The new approach that CMS is implementing bases Medicare pay rates on reimbursement in the private sector, starting in 2017. Labs must submit market data to CMS, starting in 2016. CMS must still work through which private payer rates labs must report, the time frame for reporting that data and the format for reporting it, among other considerations.

The penalty for failure to report data can be as much as $10,000 per day per unreported test.

Khani said private payer reimbursement rates vary widely because there are many kinds of labs — including independent labs, academic medical centers, hospital-based labs, small regional labs and large national providers. ACLA will emphasize that CMS should account for that wide range in pay rates.

"We do remain concerned about the expanded authority granted to CMS in the misvalued codes area by PAMA, and are closely monitoring this proposal and will actively engage on behalf of our members," said Khani, referring to the SGR bill by the acronym of its formal name, Protecting Access to Medicare Act of 2014. *— John Wilkerson*

Litigation viewed as primary way to stop state restrictions...

Georgetown Study: At Least 15 States Now Unduly Restricting Navigators

A group of researchers from Georgetown University say at least 15 states have overstepped HHS' bounds in regulating navigators and other ACA consumer assisters, but sources say CMS is unlikely to take further action to stop the states and outside legal action may be the only way to overturn the restrictions. But it is uncertain if any entities would devote resources to take the states to court, the sources add.

The authors of a recent analysis — Georgetown's Sabrina Corlette, Kevin Lucia and Justin Giovannelli — say 19 states with federally facilitated exchanges have tried to restrict assisters' work in ways that exceed federal regulations, and six states have navigator legislation pending. At least 15 states seem to be impermissibly restricting assisters' activities, they say.

HHS has said that several types of state laws prevent navigators from doing their federally authorized duties and

therefore the laws would be preempted by the ACA. These include statutes requiring assisters to refer consumers to individuals or organizations that are not required to provide impartial advice, restricting them from providing advice about benefits of a single or different health plans, requiring them to maintain their principal place of business within the state, and disqualifying providers from being assisters because they get reimbursed by insurance companies for the medical services they provide.

HHS' decision to shed light in regulations on some of the navigator restrictions they find impermissible "should have a significant impact on existing state restrictions through traditional policymaking channels and, in some instances, through litigation," the blog post states. Giovannelli tells *Inside Health Policy* that HHS provided a lot of color and context for what gets in the way of the ACA, but in general, one of the only avenues a person or organization could take is challenging the state restrictions in court.

Washington & Lee University law professor Tim Jost agrees that short of lawsuits or defense of lawsuits, there's not much that can be done other than "jawboning." The federal rules did provide some clarity, but they are also still unclear in many ways and it will probably take legal action to figure out what a lot of it means, he says.

Navigator laws in Missouri and Tennessee have already been challenged in court and advocates have also criticized Texas' restrictions. But Jost questions whether some of the organizations that have received navigator grants would even be able to devote the resources to file litigation.

CMS' list of organizations that received 2014 navigator grants shows that small businesses, Indian tribes, mental health and substance abuse organizations, primary care associations, and groups that target the health of migrant workers or homeless individuals received funding. But several universities and large hospital systems — including University of Arkansas, University of South Florida, University of Georgia, Ascension Health, University of Mississippi Medical Center, Sinai Health System, Genesis Health System, and Mercy Hospital and Medical Center — were also awarded grants.

Community health center associations and other big-name groups, such as Planned Parenthood and the United Way, received funding as well.

Apart from suing in federal court and claiming a state law violates federal law, navigators or assisters could wait for a license denial or disciplinary action from their state and resist it or file an administrative remedy, Jost says. He also imagines that regional offices of HHS are in dialogue with the states and are encouraging state insurance commissioners to comply with federal law, which could have some effect.

The restriction that has been used by the most states and might be invalid is one that dictates what kind of advice assisters can provide regarding benefits of a particular health plan or comparative benefits of different health plans, according to the Georgetown analysis. The researchers say 11 states have those type of restrictions that could violate federal rules: Arizona, Arkansas, Georgia, Illinois, Louisiana, Missouri, Ohio, Oklahoma, Texas, Virginia and Wisconsin. Additionally, Tennessee has proposed permanent rules that would do the same thing.

Five states — Arkansas, Louisiana, Montana, Ohio and Wisconsin — have placed prohibitions on navigators from receiving compensation from insurers even though that compensation is unrelated to the enrollment of individuals into plans. Federal rules do prohibit navigators and assisters from receiving compensation by insurance companies in connection with the enrollment of people into their plans, but HHS has not barred a hospital from being a navigator just because it is reimbursed by insurers for health care services.

Illinois, Iowa, Texas, Utah and Wisconsin have also imposed laws that require assisters to purchase surety bonds or insurance, and the authors argue that these restrictions "may be unduly burdensome as implemented." Consumer advocacy organizations had wanted HHS to finalize a policy saying states couldn't require navigators to carry errors and omissions insurance — which had been proposed — but HHS dropped that provision when it issued final regulations. When it was proposed, CMS wrote that requiring each navigator to carry errors and omissions insurance — which is typically only held by licensed professionals such as brokers — would mean all navigators would be considered only one type of entity the law authorizes. CMS has said at least two types of entities must serve as navigators, and at least one must be a consumer-focused non-profit. — *Rachana Dixit Pradhan*

CMS To Detail Plan For Resolving Widespread Exchange Data Issues

CMS agreed with the HHS Office of Inspector General's call that it develop and make public a detailed plan for fixing millions of inconsistencies in applications filed through the federally facilitated exchange, though based on a new HHS OIG report it appears CMS is still resolving the issues manually and several state-based exchanges also reported not having the basic capabilities needed to address discrepancies between applications and available data.

The inspector general requested data on application inconsistencies from October through December 2013, and the federal exchange provided data from Oct. 1, 2013 through Feb. 23, 2014. The report found the federal exchange was unable to resolve 2.6 million of 2.9 million inconsistencies because the CMS eligibility system was not complete. But, of the 330,000 inconsistencies CMS was capable of fixing, at that point the federal exchange had actually resolved only

about 10,000 — less than 1 percent of the total.

The inspector general was statutorily required to provide by July 1 a report on the effectiveness of safeguards for preventing the submission of fraudulent information by people applying for exchange plans or subsidies. Many of the state-based exchanges also said they could not resolve inconsistencies — Massachusetts, Nevada, Oregon and Vermont mostly attributed this inability to widespread problems with their IT systems. California's exchange said it had resolved some inconsistencies but not all of them, and Hawaii, Minnesota and Colorado said the issues were being handled by their state Medicaid offices.

The other seven state-based exchanges — Connecticut, District of Columbia, Kentucky, Maryland, New York, Rhode Island and Washington state — reported solving the issues without delay, the report says.

In the report, the inspector general repeats statements made by CMS officials that application inconsistencies do not necessarily mean a person provided inaccurate information, or is wrongly enrolled in a QHP or is receiving subsidies in error, and it's still not clear how many of those people are receiving subsidies for which they are not eligible. But even if there's an application inconsistency that required follow-up from the federal marketplace — and the inspector general says the exchange had reported it lacked system capability to process consumers' follow-up documents — that person could still enroll in a QHP.

CMS declined to say for how many of the 2.6 million unresolved inconsistencies from that point in time the FFE just accepted the applicant's attestation about their information, and how many of those people ended up enrolling in an exchange plan. However, the agency has provided more recent information about how many enrollees had inconsistencies on their applications and an agency spokesperson says the data from the IG report is outdated. As of the end of May, of the people who enrolled, roughly 1.2 million had income inconsistencies, 505,000 had immigration inconsistencies and 461,000 had citizenship inconsistencies.

Republicans continued to hammer the administration on Tuesday (July 1) over the report's findings. Along with the report on the exchanges' inabilities to properly verify and resolve issues with applicant data, the inspector general released a separate report on problems the exchanges faced in ensuring people were enrolled into QHPs in accordance with federal requirements.

"From today's reports, it appears that then-HHS Secretary Kathleen Sebelius provided a misleading certification to Congress earlier this year that the Obamacare exchanges could and would verify that individuals receiving tax credits and cost-sharing assistance are actually eligible to receive these taxpayer-provided subsidies," Senate Minority Leader Mitch McConnell (R-KY) said in a statement. McConnell and other GOP senators earlier this year said the HHS Inspector General should consider Treasury Inspector General testimony when evaluating the robustness of the federal government's income-verification and fraud-prevention systems for ACA subsidies, but the senators did not go as far as House Ways and Means Republicans, who called on the Treasury Department to stop making unverified subsidy payments.

The HHS Inspector General said CMS should develop and make public a plan on how and by what date the federal exchange will resolve the inconsistencies, and that report should include at a minimum the steps that CMS will take to clear the current backlog and how it will ensure the eligibility system can resolve inconsistencies, and how CMS will monitor the federal exchange's progress. CMS reiterated Tuesday that it anticipates working through most inconsistencies from 2014 applications this summer. However, beyond the IG's finding that CMS plans to move from its manual process to reconcile inconsistencies to an automated system "later this summer," the agency declined to offer any additional details. An agency spokesperson says CMS does not have a timeline, though the spokesperson believes the agency is using more than just a manual process at this point.

CMS also should conduct appropriate oversight of the state-based exchanges to make sure they are resolving inconsistencies in accordance with federal requirements, the HHS IG says. CMS agreed with both of the report's recommendations.

The agency has stated that the typical family of four applying for subsidies to help afford their exchange plans generated 21 separate pieces of information that required verification and could result in an inconsistency, and it has been reaching out to consumers via mail, email and phone calls to encourage them to provide supporting documentation so that inconsistencies can be resolved promptly. CMS has said that if consumers don't provide enough proof to support the information they attested to, "they will have their eligibility ended or changed to reflect what is recorded in trusted data sources."

"It's not news that healthcare.gov had tech and data issues at the outset, but we've come a long way since then. CMS is working expeditiously to resolve inconsistencies to make sure individuals and families get the tax credits and coverage they deserve and that no one receives a benefit they shouldn't," CMS spokesperson Aaron Albright said Tuesday. "We are actively reaching out to consumers to provide additional information that supports their application for coverage and verifying their information every day." *— Rachana Dixit Pradhan*

Families Docs Seek Separate E&M Codes . . . begins on page one

This year's rule proposed details for that pay code, including a pay rate: $41.92 for the code, which can be billed no more often than once a month, per patient. CMS also proposed flexibility in the supervision of clinical staff providing chronic care management.

CMS did not propose separate standards for chronic care management, even though last year's rule said this year's rule would include those standards. "Upon further review, we believe the scope of service requirements for CCM, most of which were finalized last year, would be sufficient for practitioners to deliver CCM," CMS stated. "We are proposing one additional requirement — standards for electronic health records — and seek comment on whether additional standards are needed."

Blackwelder said family physicians are working with CMS to create a separate set of evaluation and management codes for primary care physicians, but in the meantime they're happy that CMS created the pay code for chronic care management.

Another major provision of the Physician Fee Schedule proposed rule calls for notice and comment rulemaking for setting values for physician services, on which pay codes are based.

"CMS has been working with the American Medical Association's CPT Editorial Panel and Relative Value Update Committee to change the process for receiving information on new and revised codes under the misvalued code process in order to allow all misvalued code revisions to go through notice and comment rulemaking before being adopted," CMS states. "If finalized as proposed, the new process would ensure that by 2016, changes to the rates for particular services (except for those that are entirely new services never before valued under the PFS) are effective only after CMS has responded to public comment."

Lawmakers from both parties and in both chambers have been urging CMS to make public the process of setting values for physician services. The lawmakers are pushing the measure on behalf of specialists who were surprised by reimbursement cuts to their services in recent years, physician lobbyists said. Those specialists include gastroenterologists, orthopedic surgeons, nephrologists, urologists, diagnostic radiologists and pain specialists, sources said.

For decades, CMS approved the vast majority of values for physician services that were recommended by the American Medical Association's Relative Value Scale Update Committee (RUC). However, primary physicians — and several former CMS administrators — argued that the RUC undervalued primary care services and overvalued high-end specialties.

In 2011, CMS suddenly changed course, accepting nearly 30 percent fewer RUC recommendations compared to previous years. CMS had historically accepted about 90 percent of the RUC's physician payment recommendations, and in 2011 that acceptance rate dropped to about 60 percent, according to Finance Ranking Republican Orrin Hatch (UT), who at the time double checked the numbers with CMS staff.

Inside Health Policy previously reported that creating notice and comment rulemaking would erode the influence of the RUC. Some physician lobbyists said that's a misleading, or wrong, description because the changes are aimed solely at CMS, and lawmakers are responding to specialists, not the primary physicians who complain about the RUC favoring specialists. However, Julius Hobson, a senior advisor with Polsinelli Shughart, said both things can be true at the same time. Congress is responding to specialty physicians who can no long depend on CMS to approve RUC recommendations, he said, but it's also true that using notice and comment rulemaking further erodes the RUC's influence because it puts a greater emphasis on the process at CMS, even if the RUC isn't the intended target of the change. — *John Wilkerson*

In light of SCOTUS Hobby Lobby ruling...

Consumer Advocate: HHS Should Extend 'Accommodation' To Companies

HHS in the immediate aftermath of the Supreme Court's contraceptive coverage decision should extend the "accommodation" it granted for religious non-profit organizations to for-profit companies because it's the only realistic short-term solution to mitigate the ruling's consequences, the head of consumer group National Health Law Program tells *Inside Health Policy.* In its decision to scale back the ACA's contraception coverage requirement, the Supreme Court's conservative wing suggested that HHS' accommodation that lets some religious non-profit organizations avoid directly providing the benefit may have actually hurt the government's argument that Hobby Lobby must comply with the requirement, because Hobby Lobby could have been granted the same leniency.

While the ACA requires that plans cover a wide range of preventive services without imposing cost-sharing on enrollees, HHS from the outset said churches and other houses of worship are completely exempt from the contraception mandate. Amid an uproar in 2012, the administration proposed an "accommodation" for religious-based non-profits that allowed them to get out of directly paying for that benefit for their female employees. The policy was designed to appease organizations such as faith-based hospitals and universities.

In the *Burwell v. Hobby Lobby Stores, Inc.* opinion on Monday, the high court declined to address the question of whether the HHS accommodation would stand up to the court's scrutiny. But litigation continues to circulate throughout

the court system, as religious non-profit organizations argue that the administration's accommodation does not go far enough. Elizabeth Taylor, executive director of the National Health Law Program, even acknowledges that the accommodation has its shortcomings and uncertainties, but she said extending that policy is the only realistic short-term solution to ensure women are getting the coverage they are still entitled to.

Under the accommodation, for a religious non-profit employer that is fully insured and opposes paying for the contraceptive coverage, an issuer providing the group health insurance coverage for that organization assumes the sole responsibility for providing separate payments for contraceptive services directly for plan participants. If an eligible non-profit organization is self-insured, a third-party administrator would become an ERISA plan and claims administrator solely for the purpose of providing payments for contraceptive services for the people enrolled in that plan. This would be done at no cost to plan participants or to the eligible non-profit organization; and HHS wrote in regulations that the TPA can provide such payments on its own or it can arrange for an issuer or other entity to provide such payments.

"The employees of these religious non-profit corporations still have access to insurance coverage without cost-sharing for all FDA-approved contraceptives; and according to HHS, this system imposes no net economic burden on the insurance companies that are required to provide or secure the coverage," Justice Samuel Alito wrote in the high court's majority opinion.

"Although HHS has made this system available to religious nonprofits that have religious objections to the contraceptive mandate, HHS has provided no reason why the same system cannot be made available when the owners of for-profit corporations have similar religious objections," he added.

Hobby Lobby, during oral arguments, would not take a position on whether extending the accommodation provided to religious non-profits would be sufficient. Following the decision, Adele Keim, legal counsel at the Becket Fund for Religious Liberty, which represented Hobby Lobby in the case, also would not comment on the company's position on the accommodation. However, she did question whether the Supreme Court would accept a move by HHS to extend that policy to for-profit companies.

White House Press Secretary Josh Earnest declined to elaborate on options the White House is considering, saying the administration was still assessing the impact of the decision and how many employees are affected. As the White House gathers information it may be in a better position to consider the range of options available to the president, but it is the administration's view that Congress needs to take action, Earnest said.

Taylor agreed that while the National Health Law Program believes the short-term solution is for HHS to broaden the accommodation, Congress needs to come up with the real solution in response to the ruling. One of those things could be for Congress to set limits on RFRA directly so that for-profit companies cannot claim that they are "persons" capable of exercising religious beliefs under that law.

Senate Democrats are already moving to blunt the ruling's impact. Senate Majority Whip Dick Durbin (D-IL) said he would soon introduce legislation requiring companies using the Supreme Court's decision to deny or limit contraception coverage to disclose that policy to employees and applicants for employment.

"Workers have a right to know if their employers are restricting the availability of a full range of family planning coverage," he said in a statement.

Sen. Patty Murray (D-WA) also said in a statement that she would "work with my colleagues and the administration to protect this access, regardless of who signs your paycheck." Murray's office did not respond to questions as to whether she believes the administration should extend the accommodation being provided to religious non-profit organizations to for-profit companies as well.

The central question in the case was whether Hobby Lobby and Conestoga Wood Specialties' owners' religious objections to providing certain contraception coverage to their female employees extended to the corporation itself. Under the Religious Freedom Restoration Act the employer is required to prove that it is a "person" capable of religious belief and the ACA's requirement to provide health insurance that covers contraception at no out-of-pocket cost to the employee is a substantial burden. On the other side, the government had to prove that it has a compelling interest in providing health insurance coverage for preventive services, including contraception, and that the government is meeting the compelling interest in the least restrictive way. On Monday, the court said the government failed to meet the least-restrictive standard.

In a scathing dissent, Justice Ruth Bader Ginsburg wrote, "Until this litigation, no decision of this court recognized a for-profit corporation's qualification for a religious exemption from a generally applicable law, whether under the Free Exercise Clause or RFRA. The absence of such precedent is characteristic of natural persons, not artificial legal entities."

"The court's determination that RFRA extends to for-profit corporations is bound to have untoward effects. Although the court attempts to cabin its language to closely held corporations, its logic extends to corporations of any size, public or private. Little doubt that RFRA claims will proliferate, for the court's expansive notion of corporate personhood — combined with its other errors in construing RFRA — invites for-profit entities to seek religious-based exemptions from

regulations they deem offensive to their faith," she continues.

The court in its decision said closely held corporations cannot be required to provide the contraception coverage at no cost to their female workers, but Sarah Lipton-Lubet, director of reproductive health programs at the National Partnership for Women & Families, says it's still not really clear how many employees this could have negative consequences for.

"That's part of what makes the ruling today so dangerous," she said. She only said the group was "looking at all options" to address the decision, but declined to offer specifics.

The government could decide to assume the cost of providing contraception to women who are unable to obtain the coverage because of their employers' objections, the majority opinion stated.

Keim says she believes the least-restrictive means for contraception coverage to be provided to the female employees in question would be for the government to pay for the coverage itself, but that has never been proposed. The court's opinion was telling, in that the government should not be picking winners and losers when companies share the same religious objection to paying for that benefit.

But Taylor takes issue with the court's suggestion, as Title X of the Public Health Service Act is the only dedicated source of federal funding for safety net family planning services. Under Title X, HHS has a hard enough time meeting low-income women's needs, and there just aren't enough resources to meet the needs of all the women impacted by Monday's decision, she said. — *Rachana Dixit Pradhan*

Duals Demos Double Enrollment In One Day . . . begins on page one

in Los Angeles County began July 1. That also was the date of the third round of passive enrollment in Massachusetts, which is phasing in enrollment on a quarterly basis. Illinois began its second round of passive enrollment on July 1, and Virginia began its first round of passive enrollment. Also, several thousand beneficiaries voluntarily enrolled for the demo that Ohio is running.

The demos are designed to coordinate care for beneficiaries who are covered by Medicare and Medicaid, called dually eligible beneficiaries. Advocates for Medicare and Medicaid beneficiaries support health care coordination, but they worry that automatically enrolling patients in managed care plans could cause beneficiaries to lose providers and important health care services. They worry that the demonstrations are designed to save money immediately, although at least one state, Minnesota, does not have to reduce Medicare spending. They also believe that the demonstrations are too large to be considered pilots — California plans to move nearly half a million beneficiaries into Cal MediConnect — so there is no going back, even if they don't work.

Beneficiary advocates are uneasy with passive enrollment because beneficiaries are automatically enrolled in new managed care plans with different provider networks and services. CMS and the states call it passive enrollment because residents may opt out after automatically enrollment, but beneficiary advocates worry that many will not know to opt out and might not realize what's been changed about their coverage.

The CMS official said there is a transition period during which beneficiaries are guaranteed access to the providers and services under their previous coverage.

In part because of its size, consumer groups have focused much of their attention on California. In February, six consumer advocacy organizations, including the National Senior Citizens Law Center, asked state officials to suspend the demo because Medicaid residents weren't given adequate notice of coverage changes and call centers were unprepared. A few weeks ago, the National Senior Citizens Law Center followed up with a request that state and CMS officials suspend the passive enrollment aspect of the demo because "unfortunately, many of our concerns about the capacity and readiness of enrollment systems have been realized."

"New problems are reported to our organization from the field every week and, increasingly, those problems include reports of seniors and people with disabilities failing to receive needed care and/or losing access to their Medicare doctors," the group wrote to Medicare-Medicaid Coordination Office Director Melanie Bella and California Department of Health Care Services Director Toby Douglas.

CMS and the states are monitoring the duals demos, the agency official said, and there have been problems with enrollment, mostly in California. CMS and state Medicaid officials are fixing those problems and for the most part the problems confused beneficiaries and did not lead to beneficiaries losing access to providers or services, the official said. For example, some beneficiaries were assigned to wrong plans, then quickly reassigned to the right plans. However, even when they were re-enrolled without a break in access to care, they still had to be sent notification of having been disenrolled, which the official said needlessly confused many beneficiaries.

The official said it's too soon to say whether demos are hitting savings goals or changing service-use patterns. However, based on early indicators, the demos are running smoothly and many beneficiaries are receiving services they previously were not getting, such as early comprehensive assessments. — *John Wilkerson, Rachana Dixit*

Nadler, DeGette Plan Legislation To Neutralize High Court's Hobby Lobby Ruling

Reps. Diana DeGette (D-CO) and Jerrold Nadler (D-NY) said Wednesday (July 2) they are working on a legislative response to the Supreme Court's Hobby Lobby ruling that will ensure employers cannot use the Religious Freedom Restoration Act to avoid covering employees' contraceptives.

A DeGette staffer says the two lawmakers were on the phone "minutes" after going through Monday's opinion. The two made the announcement Wednesday due to the overwhelming interest from the public and media in next steps, the staffer said. The office wanted to make it very clear that a legislative solution is forthcoming.

The announcement notes that while the House is not in session, the lawmakers have begun working with colleagues to draft legislative language, and expect to introduce two pieces of legislation, each addressing one of the issues raised by the high court's decision.

The staffer says it's too early to even speak conceptually about what the legislation will entail. It's also too early to place a timeframe on the legislation's introduction, but the goal is to have it out as soon as possible, the staffer adds.

"Congress never intended RFRA to be used by employers as a means of interfering with private health care choices of their employees," DeGette and Nadler, who was a leader in the fight to enact RFRA in 1993, said in a statement. "The law kept in place the core principle that religion does not excuse for-profit businesses from complying with our nation's laws. It is now up to Congress to ensure that the Court's ruling does not interfere with access to critical preventive health care services.

"While the majority opinion misunderstands the importance of contraceptive coverage for women's health when Justice Alito wrote that their decision would have 'precisely zero' impact, we believe Congress can and should take action," Reps. DeGette and Nadler added. "In reality, women working for many for-profit corporations will now need new insurance coverage for contraception, and we can ensure they can still access this essential health service through legislation."

On Monday, the court said the government failed to meet the least-restrictive standard under RFRA, and said "closely held" corporations cannot be required to provide the contraception coverage. But, the government could decide to assume the cost of providing contraception to women who are unable to obtain the coverage because of their employers' objections, the opinion stated.

"There are other ways in which Congress or HHS could equally ensure that every woman has cost-free access to the particular contraceptives at issue here and, indeed, to all FDA-approved contraceptives," Alito wrote.

Following the ruling, Elizabeth Taylor, the head of the consumer group National Health Law Program, told *Inside Health Policy* that the best short-term solution would be for HHS to broaden the "accommodation" on providing contraceptives that is currently available for non-profits that object to the coverage. Taylor further said that Congress needs to come up with the real solution in response to the ruling, and suggested that lawmakers could set limits on RFRA directly so that for-profit companies cannot claim that they are "persons" capable of exercising religious beliefs under that law.

Senate Democrats have indicated that they intend to pursue legislation as well. Senate Majority Whip Dick Durbin (D-IL) said he would soon introduce legislation requiring companies using the Supreme Court's decision to deny or limit contraception coverage to disclose that policy to employees and applicants for employment.

"Workers have a right to know if their employers are restricting the availability of a full range of family planning coverage," he said in a statement. Sen. Patty Murray (D-WA) also said in a statement that she would "work with my colleagues and the administration to protect this access, regardless of who signs your paycheck." — *Amy Lotven, Rachana Dixit Pradhan*

Auto-Renewal Could Be Coupled With Message To Shop In Open Enrollment

Health experts agree that the Obama's administration's proposed automatic renewal policy for consumers that enrolled in exchange plans through healthcare.gov is a smart move that will mitigate potential disruptions in coverage and care, but they also suggest that in order to spur healthy competition it must be coupled with aggressive messaging that pushes consumers to shop for the best plan during open enrollment.

Last month, the administration unveiled a highly anticipated policy proposal that CMS says would allow a majority of consumers to easily maintain their existing tax subsidies and keep their current plan — as long as the plan in question has not been discontinued by the insurance company. The proposal, which is supported by consumer groups and insurers, is seen as critical to ensure that the millions of Americans who enrolled during the first open enrollment period don't drop their plan because of a complicated renewal process.

The auto-renewal a really good move, says Karthik Ganesh, executive vice president of QualCare, Inc. QualCare has health plans in New Jersey, New York and Pennsylvania. The company also supplied the provider network and operations for the CO-OP plan (Health Republic Insurance of New Jersey) set up the by the Freelancers Union in that state.

But, Ganesh said, the challenge will be for plans that want to come in and compete with existing insurers. It's been shown that in Medicare, it's very tough for people to break away from their current plan, he said. According to a Kaiser Family Foundation analysis of Part D open enrollment from 2006 through 2010, an average 13 percent of enrollees switched plans per year. Additionally, the study found that seven out of 10 beneficiaries enrolled in Part D plans did not voluntarily switch plans in any of the four open enrollment periods.

Ganesh says he expects that there will be much more aggressive marketing from insurers in the coming years, especially now that healthcare.gov has stabilized.

Asked if there were concerns that auto-enrollment could depress competition in later years, an industry source says that it is too early to speculate.

"(I) think we need to see how this one goes in terms of how many people will stay in their current plans or switch to another, but really, it will depend on the consumer," the source says. "This is a market that has had tremendous amount of movement in the past — people coming in and going out with jobs, changes in circumstances and more. This latest rule provides important stability for consumers but they also have the option to change plans if they want," the source adds.

Avalere Health's Caroline Pearson says the renewal process CMS has outlined is certainly what the industry wanted. It has the benefit of creating continuity of care for enrollees, especially because the narrow networks that are prevalent among exchange plans make it more likely that switching plans would mean switching doctors, she says.

Pearson says she's not convinced that the renewals would blunt competition — and points out that Part D rates have remained relatively low. It seems that in the existing market, plans are still sufficiently concerned about keeping consumers that they'll be angling to have competitive prices, she says. People are price sensitive enough that they will not take premiums going higher and higher without taking action, and the threat of a lower-cost alternative on the market will keep plans priced competitively, Pearson adds.

Additionally, as Avalere had pointed out in a recent analysis, many consumers will face higher premiums in 2015 because the plans that currently are the second-lowest-cost silver plans — which are used as the benchmark to establish subsidy amounts — will not keep that status next year. Consumers should be encouraged to re-evaluate their plans and look for other products, she says.

Joel Ario, the former head of HHS' exchange office who is now a managing director with Manatt Health Solutions, also believes that encouraging the consumer to shop is key.

"Insurance commissioners routinely produce consumer education materials demonstrating that consumers can save money on their insurance by shopping around at renewal," says Ario, who also served as insurance commissioner in Pennsylvania and in Oregon.

Ario sees car insurance as the best historical example, and notes that the leading brands have vigorous price competition that can produce savings of 20 percent or more for the savvy shopper.

"Yet, the reality is that most consumers do not shop and all states allow automatic renewal as the best way to prevent coverage gaps," he says. "Public and private exchanges will generate the same kind of price competition for health insurance (hopefully with more local brands rooted in community-based delivery systems giving the national brands a run for their money) and there should be aggressive public education campaigns to encourage shopping at renewal."

Ario says it would be a "huge mistake" to not offer auto-renewal to as many consumers as possible.

"The bottom line is that we should encourage shopping but rely on auto renewal as the best way to avoid coverage gaps," he adds. *— Amy Lotven*

OMHA Tests Solution To Cut ALJ Backlog . . . begins on page one

parties will sign the deal at a settlement conference session and the claims will be pulled from the ALJ's backlog. But CMS and the providers must be willing to make a deal at the conference, or the claims go back in the ALJ queue.

In 2013, OMHA slapped a moratorium on assigning most appeals to administrative law judges until they reduce the appeals backlog, and while OMHA is now assigning some cases that have been appealed, there is a 20-24 week wait before the new appeals are entered into the system, and up to another 28 months until an ALJ is assigned to the case. The American Hospital Association sued over the appeals backlog to compel HHS to meet the 90-day deadline to review appeals at the ALJ level.

The House Oversight and Government Reform health subcommittee is expected to examine the backlog and problems with the appeals system on Thursday (July 10). Chief Administrative Law Judge Nancy Griswold is set to testify.

The only claims eligible for the mediation pilot, which was one potential alternative dispute resolution option floated at a February forum on the ALJ backlog, will be Medicare Part B claims filed in 2013 that are waiting to be assigned to an ALJ. This means that hospitals' inpatient medical necessity denials will be ineligible for the pilot.

Appeals must be initiated by a Medicare provider or supplier. OMHA says that beneficiary-initiated appeals that reach the third level of the appeals process are not included because those appeals are already being prioritized for a

hearing before an ALJ.

Medicare Part A claims are not eligible for the process at this time, OMHA says, and neither are Medicare Part C, Medicare Part D or Part B late enrollment penalties.

"The facilitator does not make official determinations on the merits of the claims at issue and does not serve as a fact finder, but may help the appellant and CMS see the relative strengths and weaknesses of their positions," a fact sheet on the pilot says.

The Recovery Audit Contractors are meeting with CMS to get more information about the pilot and to understand its scope and impact, *Inside Health Policy* has learned. A spokesperson for the American Coalition for Healthcare Claims Integrity, which represents RACs, said, "Our coalition appreciates the agency's proposed strategy to alleviate the Medicare appeals backlog." The group hopes that the new option will provide relief to integrity contractors and providers, and increase the efficiency of the appeals process, the spokesperson added.

One lobbyist following the issue said it was good to see the pilot come to light, as stakeholders hadn't heard much from OMHA since the February forum. But, given the restrictions on which claims are eligible, the pilot may have only a modest effect on the backlog, the lobbyist added.

A hospital lobbyist following the issue agreed that the pilot is not likely to have much of an effect on the backlog, as providers likely will wonder if it will be worthwhile given CMS' poor track record in the area.

But Kim Brummett, vice president for regulatory affairs at the American Association for Homecare, said the pilot is worth a shot despite the outstanding questions.

Under the pilot, providers or suppliers must include all pending appeals for the same item or service in the mediation. For example, if a supplier has 50 wheelchair appeals pending, they must submit a request for a conference on all 50, OMHA says. All services within a single appeal also must go into the settlement conference together. Brummett says that often DME appeals are over the same types of issues across multiple cases, so the pilot potentially could cut down on the number of DME cases in the backlog if suppliers start to see acceptable outcomes.

But the pilot doesn't deal with the underlying problems in the appeals system, Brummett said. The second level of appeals will continue denying cases those appealing believe should be overturned, Brummett added. The Center for Medicare Advocacy recently sued CMS over denials at the lower levels of appeals. The pilot also won't help with providers and suppliers repeatedly appealing the same types of denials, or contractors carrying out more audits — and creating more appeals — than the ALJs can handle, Brummett said. — *Michelle M. Stein*

Vitals: A Health Policy Blog

Excerpts of Inside Health Policy Blogs

CMS: SHOP Plans Will Not Auto-Renew

Coverage for small employers that the business obtained through the federally facilitated SHOP exchange will not automatically renew, CMS says in a recent frequently asked questions document. CMS plans to outline the renewal process in a future notice, the agency said in the FAQ.

The information comes as the administration recently proposed that coverage for most people enrolled in the individual market exchange will renew automatically, assuming the plan has not been discontinued by the insurer.

It is unclear how many businesses will be affected by the SHOP decision because the agency has not released enrollment figures. Insurers are slated to begin sending FF-SHOP enrollment data to CMS in August, but CMS has not said if it intends to release the information at that time. — *Amy Lotven*

HHS To Open 150 Additional Community Health Centers

HHS announced Tuesday (July 8) it will open an estimated 150 new community health centers across the country with $100 million in grants from the Affordable Care Act. The new centers will add to the more than 550 new community health centers opened during the last three years through the ACA, according to the agency.

Health Resources and Services Administration Administrator Mary Wakefield said that since last fall health centers provided enrollment assistance to more than 4.7 million people, and she is pleased the ACA supports establishment of additional health center sites to provide more places for the newly insured to receive needed services. The maximum amount each site can receive is $650,000, according to HRSA's website.

In June, HHS also awarded $300 million in grants to community health centers to expand primary care capacity for new patients and to cover oral, behavioral, pharmacy and vision services for new and existing patients. — *Michelle M. Stein*

NCQA Ventures Into Ambulatory Care

The National Committee for Quality Assurance (NCQA) is venturing into ambulatory care by developing standards to evaluate telemedicine providers, worksite clinics, urgent care clinics and retail clinics.

The new NCQA program, tentatively named Patient-Centered Connected Care Recognition, will assess how well ambulatory care facilities coordinate with medical homes and other providers. The program will look at whether providers are involving patients and their families in treatment deci-

sions, promoting self-care, providing culturally appropriate care and committing to continuous quality improvement, according to an NCQA release. — *John Wilkerson*

Veterans Affairs Not Factoring Cost Of Sovaldi Into Treatment Decisions

In light of the high cost of the Hepatitis C drug Sovaldi, David Ross, director of the Veteran's Affairs HIV, Hepatitis, and Public Health Pathogens Programs, said the VA will soon release a formal statement that the VA does not factor the cost of drugs into treatment decisions.

In March, the VA placed Sovaldi on its formulary, and it is targeting treatment to sicker patients who are more likely to die from the infection and the condition of their livers. There is a high prevalence of people with Hepatitis C among veterans, Ross said. Three months following FDA approval of the drug, 900 veterans were on taking it, and now more than 2,000 VA patients are on the drug, Ross said at a event convened by the Center for Medical Technology Policy. The VA estimates that veterans account for 175,000 of the more than 3 million Americans believed to be infected with Hepatitis C. — *John Wilkerson*

Health IT Subgroup May Delay Sending Meaningful Use Suggestions To Committee

Members of the Quality Measures Workgroup of the Health IT Policy Committee decided Tuesday (July 1) to continue working on recommendations for CMS meaningful use Stage 3 standards and possibly delay their report to the Policy Committee, which had been due July 8.

During their July 1 meeting, work group members realized that in filling out a survey to prioritize standards that many were working with different definitions for terms and understandings of questions on the survey. In particular, group members were confused as to whether core measures they recommend to the committee will be requirements or recommendations that vendors must meet in order to fulfill meaningful use Stage 3 standards. In stage 1, core measures are required, and in stage 2, core measures are recommended.

The group members said they would continue working toward a consensus. They said they might schedule another meeting before July 8 to complete their work and they may need to wait until a later date to submit their report.

— *Todd Allen Wilson*

Oklahoma Secures Medicaid Waiver Extension, Puts Off Expansion

Oklahoma Gov. Mary Fallin (R) has secured another extension from CMS of its "Insure Oklahoma" program, a Medicaid premium assistance waiver aimed at helping primarily low-income adults pay for employer-sponsored health insurance or an individual plan. The program resembles goals of the ACA's Medicaid expansion because it broadens access to insurance for low-income adults, but Fallin has been steadfast in not supporting the ACA provision.

Fallin made the announcement just days before the White House released a new report criticizing the 24 states that have not expanded Medicaid to date. The report said those states, if they had participated as of Jan. 1, would have received an additional $88 billion in federal dollars through 2016. The expansion also would have boosted employment in those states by 85,000 jobs this year, and 184,000 jobs next year, the report estimated.

But the latest extension of the Insure Oklahoma waiver means Oklahoma almost certainly won't consider expanding Medicaid before 2016. Fallin, in announcing the extension, said she would continue to push the federal government to make the waiver permanent.

Oklahoma had already received a one-year extension of the program to the end of this year, but under the latest approval the program can stay in place until the end of 2015. The waiver is funded by the state's tobacco tax and is matched with federal dollars, though Oklahoma cannot receive the higher match that's authorized by the ACA for Medicaid expansion.

Originally, the program provided premium assistance to low-income adults up to 200 percent of poverty, but, when Oklahoma got its first extension, the eligibility criteria was slightly changed for people trying to get individual health insurance. Now, the eligibility criteria for that plan is up to 100 percent of poverty, and people with incomes higher than that will need to go to the Oklahoma exchange — which is run by the federal government — to get subsidized health insurance.

Like Oklahoma, Indiana had previously received an extension of its existing non-expansion 1115 waiver, the Healthy Indiana Plan. But it has since changed course. Indiana has agreed to participate in Medicaid expansion and on July 1 submitted its waiver proposal — for Healthy Indiana 2.0— to HHS. — *Rachana Dixit Pradhan*

E&C Addresses Clinical Trials, Patient Input In 'Cures Initiative' Hearings

The House Energy and Commerce health panel will probe how clinical trials affect drug development costs and patients' ideas on ways to speed products to market at a new round of product innovation hearings next week. On Wednesday (July 9) the panel examined opportunities to modernize clinical trials and accelerate the development of new cures and treatments; and on Friday (July 11) lawmakers will solicit feedback from patients on how to expedite the drug discovery, development and delivery process, the panel announced Thursday (July 3).

The hearings come as debate continues over what steps FDA should take to speed approval of innovative products — with some industry and patient stakeholders pushing the agency to use accelerated approval pathways more frequently and others raising concerns that increased reliance on post-market trials could pose a risk to patients. The subcommittee notes that some stakeholders recently testified that clinical trials are the "greatest cost driver of biologic and drug development."

Top FDA officials, however, have said that innovation in and of itself is not enough and emphasized the agency will

continue to prioritize safety and effectiveness data. The agency also recently voiced concerns about proposals to speed innovation by eradicating phase III clinical trials and sought researchers' help in rebuffing efforts to overhaul the current process.

Patient groups have been targeted by lawmakers, drugmakers and insurers in ongoing debates about drug pricing and innovation. The drug pricing issue has led some groups to leave the National Coalition on Health Care, which is campaigning against high drug prices.

The National Health Council — which includes both drug industry and patient groups — also has been heavily involved in the drug innovation debate. The group recently testified that two major barriers preventing promising medicines from reaching patients are: "a complete lack of patent protection," and "the lack of a predictable post-approval period of patent protection."

E&C has held several hearings and two roundtable discussions and released four white papers on a variety of topics since kicking off its innovation initiative in April. The committee plans to introduce legislation resulting from the initiative sometime next year. — *Stephanie Beasley*

New Business Screens Large Employers' Medicaid-Eligible Workers

A new business that would insulate large employers from the cost of providing health coverage to all workers while simultaneously allowing them to avoid employer mandate penalties by helping low-income workers enroll in Medicaid appears legally sound and could offer a win-win for employers and employees, several sources tell *Inside Health Policy*. BeneStream is led by New York-based health policy expert Ben Geyerhahn and boasts an advisory board of well-known figures in healthcare, including SEIU President Emeritus Andy Stern.

On Tuesday (July 2), BeneStream announced it had gleaned $1.58 million in first round financing seed money that will be used to prepare for demand related to implementation of the employer mandate. BeneStream works by screening low-income workers to see if they are eligible for Medicaid, and then helping them to enroll. The company is focusing on states that have expanded Medicaid eligibility under the ACA.

Geyerhahn says the concept behind the company, which was initially funded by a grant from the Ford Foundation, was to find ways to make it easier for low-income workers to gain access to all the benefits to which they are entitled. These are people who really can't afford to pay premiums for employer-sponsored coverage, he said.

Geyerhahn — who is also a member of an advisory board for the New York state-based exchange — explains that employers have 90 days in which to offer coverage to a new hire, and the real value is to know an employee's status prior to the end of that waiting period. The conversation could then be centered upon whether the employee wants to stay on Medicaid — which would generally pose little to no costs to the beneficiary — or switch to the employer-sponsored plan.

Knowing that an employee is on Medicaid could also help if companies are required to auto-enroll employees, he says, because employers would be able to tell those workers that they can opt-out instead of potentially having a large portion of their paycheck taken for coverage that they do not need. (The health law requires employers with 200 or more workers to auto-enroll employees, however the provision has yet to be implemented and some business groups are lobbying for its repeal.)

"The Affordable Care Act was designed to ensure that everyone has access to health coverage and, by doing so, lower the healthcare cost burden placed on taxpayers," Stern said in the BeneStream funding announcement. "To accomplish this, it's essential that we ensure that low-income workers use this benefit that they're entitled to or they are likely to avoid coverage altogether," he said.

"Our investors are excited about the win-win value proposition of enrolling lower income-workers in Medicaid. Businesses will do right by their workers while saving between 80 percent and 90 percent of their insurance premium costs," Geyerhahn added in the release.

Geyerhahn points out that between 60 million and 70 million people could be eligible for Medicaid in the coming years. He said BeneStream has already worked with restaurants in New York, and said home health and nursing homes — which have slim margins and employ low-income workers — could especially benefit from the model.

The employer mandate requires firms with at least 50 employees to offer minimum essential coverage to full-time workers or to pay a fine of $2,000 per worker. Employers that offer coverage that does not meet the actuarial value thresholds or would cost workers more than 9.5 percent of household income would be fined $3,000 per worker that enters the exchange and receives a subsidy. But the penalty is not assessed if that worker is eligible for Medicaid, explains Washington & Lee law professor Tim Jost.

Jost — who reviewed BeneStream's investment announcement — said that the business appears to hew to the law. The key is that the employer would still have to make the offer of coverage to the worker.

However, a potential issue could be the prohibition on discrimination in favor of highly compensated workers. That prohibition has been in effect for self-insured plans, and the ACA extends the prohibition to fully-insured plans. Implementing rules for that provision have not yet been released.

"I could imagine if you have a company with a handful of people in good private plans and the remainder on Medic-

aid, it could be a problem," he said.

A Democratic consultant who read BeneStream's release adds that while it may be a "little untoward" in that the company focuses on savings to businesses, Medicaid is a benefit that should be taken up by those who are eligible.

"It's likely better coverage and more subsidized than employer coverage, so it's a really good idea for low-wage workers. That's why I like what they are doing," the source says.

"I think it's a good idea," says Chris Condeluci, a former GOP Finance Committee staffer who is now an attorney with the law firm Venable. The administration should view it as a positive outgrowth within the private sector that can facilitate enrollment, he adds.

What the law has essentially done is create various "buckets" of health coverage with different eligibility categories — Medicaid eligibility, subsidy eligibility, and eligibility for employer-sponsored plans — and the administration wants to use each category to facilitate coverage expansion.

"If a private sector solution can identify which Americans are eligible for which bucket - then that is a good thing," Condeluci says. "Especially since the individual may not be able to ascertain their coverage options that easily."

Condeluci said he would only be concerned about the model if businesses compelled employees to enroll in Medicaid.

Additionally, he said addressing Medicaid eligibility through the private sector could help reduce the administrative burden for exchanges and state Medicaid agencies.

Condeluci, who works with private exchanges and web-broker entities, says employers are starting to take a "holistic" approach to providing health benefits to employees. Full-time employees can access employer plans through a private exchange, and part-time, seasonal or temporary workers who are not offered an employer plan can access an individual policy offered on the federally facilitated exchange through a web-broker entity. Helping with Medicaid enrollment could be another component of this approach, he says. *— Amy Lotven*

Consumer Rep: House Innovation Initiative Gets One-Sided Patient View

Some patients advocates worry that the House Energy and Commerce Committee is favoring industry-backed patient groups as part of its new medical production innovation initiative, said Diana Zuckerman, president of the National Center for Health Research, which advocates consumer health and safety through medical research. The advocates are beginning to reach out to lawmakers to voice concerns that E&C is engaging patient groups that favor accelerated approvals and excluding others that are more focused on maintaining safeguards to protect public health, she said.

The committee's health panel is slated to hold a hearing Friday (July 11) to solicit patient perspectives as part of its 21st Century Cures Initiative, but the panel hasn't said which groups have been invited to testify. Zuckerman said some patient groups worry they will be excluded. Up to now, Zuckerman added, the committee has mostly heard from groups focused on identifying ways to expedite product approvals.

The panel says it hopes to get patient feedback at the hearing on how to accelerate the pace of cures and to include patient input into the benefit-risk framework. The committee also released a white paper in May seeking patient feedback.

Groups like the National Organization for Rare Disorders have been pressing FDA to speed approval of innovative cures and treatments but NCHR is urging lawmakers not to ignore the safety and effectiveness issues that could result from using smaller trial sizes — a key component of accelerated approval pathways. FDA has also opposed proposals to do away with phase III clinical trials.

Marc Boutin, executive vice president for the National Health Council, whose diverse membership includes patient advocacy groups as well as the drug and biotechnology industry trade groups, suggested the committee could unify the diverse patient group community if it focused on defining patient engagement and working to establish validated methods for including their perspective in the discovery, development and delivery process. He said a discussion focused on how much risk or uncertainty some groups are willing to accept could be divisive as rare disease groups are especially more likely to advocate for higher risk tolerance — a view that is not be shared by all.

The committee has already heard testimony from the NHC as well as Friends of Cancer Research and NORD, which tout themselves as patient groups. Yet, Zuckerman notes that those groups have focused more on speeding approvals than implementing safeguards. And it's unclear what other groups the committee has consulted and there is concern from some consumer advocates that lawmakers are only hearing from those with strong ties to industry, she said.

"Neither we nor any of the groups we work with have been contacted," Zuckerman said. "They're talking to some patient groups, but we don't know who they are. There is more than one point-of-view. There are a lot of people in between, but it seems like the Energy and Commerce Committee has focused on the groups who are pushing for faster approvals and not pushing for better safeguards." Zuckerman said some groups are contacting the committee, although she declined to provide names.

She further warned that stakeholders should be concerned that efforts to push FDA toward establishing more expedited approval pathways could counter efforts to gather more demographic subgroup and sex-specific data as well as moves toward personalized medicine. These new pathways speed approvals by relying on the use of smaller clinical trial

populations. As you diminish trial sizes there is greater possibility of having fewer women and people of color, Zuckerman said.

Peter Lurie, FDA's acting associate commissioner for policy and planning, also recently said the agency is skeptical of proposals to expedite drug approvals by lowering clinical trial data standards.

E&C has held several hearings and two roundtable discussions and released four white papers on a variety of topics since kicking off its innovation initiative in April, and the committee plans to introduce legislation next year.

The National Health Council is one of the groups that has been heavily involved in the drug innovation debate. Boutin said the group feels like it has much to add to the discussion since it has worked extensively on the issue of incorporating patient perspectives in the development process.

"There are widely different perspectives on risk tolerance across the spectrum. The question is how do you develop and use validated methods," he said. "If you look at a rare disease population where you have a condition that means you certainly are going to die after seven years...your tolerance for risk may be higher. We don't want to define the tolerance, you want to define the mechanisms to gauge that tolerance. If you do that, we're all together."

Patient groups also are being targeted by lawmakers, drugmakers and insurers in ongoing debates about drug pricing. — *Stephanie Beasley*

Patients May 'Value' Hep C Drugs Differently Than Insurers, Consultant Says

Researchers should get patients' take on what they consider "value" if comparative effectiveness research is to accurately compare drugs, such as the high-priced blockbuster Sovaldi and the Hepatitis C drugs that are expected to follow it, said Donna Cryer, who represented several brand-drug companies as well as patient groups at her former consultancy firm CryerHealth. Cryer recently started the Global Liver Institute.

Cryer, a liver transplant recipient, also has served as a patient representative to FDA and became the first patient to chair the board of the American Liver Foundation, according to CryerHealth's website.

The Center for Medical Technology Policy's Green Park Collaborative and the Institute for Clinical and Economic Review hosted a web conference on Monday (July 7) to talk about what evidence is needed to demonstrate effectiveness and value of new drugs to treat Hepatitis C. Most panelists said more real-world evidence is needed, which policymakers have been saying for several years.

However, the panelists each came at real-world evidence development from a different perspective.

Cryer said value is often measured in terms of value to the health care system and not value to patients. Patients value simpler drug regimens for reasons that are of little value to health insurers, she added. Easier regimens increase medication adherence, which slows infections resistance to drugs. Cutting down on side effects is enormously valuable to patients, she said, adding that some so-called side effects can be life threatening. She also said researchers should consider savings that are not easily estimated, such as avoiding the costs of treating patients who suffer from liver failure and reducing absenteeism at work.

Cryer also took the opportunity to chide those who advocate for making patients wait for treatments until they are sufficiently ill, and she asked whether there are other examples of insurers not treating people because a type of infection hadn't made people sick enough.

Gregg Alton, executive vice president of corporate and medical affairs at Sovaldi-maker Gilead Sciences, said the company is studying patient-reported quality-of-life outcomes, including whether the drug reduces fatigue and allows people to work more days.

CMTP founder and CEO Sean Tunis emphasized that the purpose of the event was to discuss the evidence needed for determining value and not to debate the price of Sovaldi or policies that states and private insurers are using to deal with the product's $84,000 treatment regimen, which is on top of other drug costs.

Institute for Clinical and Economic Review President Steve Pearson said it would be good to track people after they've been cured of Hepatitis C because it's not clear whether, or to what extent, they're actually less likely to develop liver cancer. He also said it would be nice, although he isn't sure whether it's plausible now that Sovaldi is on the market, to study the health status of people infected with Hepatitis C who remain untreated and to do placebo-controlled tests of Hepatitis C drugs. Many expect FDA to approve additional Hepatitis C drugs in the near future, and Pearson said he'd like head-to-head studies of those drugs that include patient characteristics. Like many people, Pearson wants to know how well drugs taken outside of clinical trials work.

Alton said companies tend to run studies that tease out differences among subpopulations or long-term effectiveness and safety after multiple drugs are on the market and companies are vying for market share. He also said it remains to be seen whether industry or some other group will do these studies.

Public health consultant Michele Manos said many of the more than 3 million people infected with Hepatitis C are, or are nearly, Medicare age so it might be up to the government to pay for comparative-effectiveness studies. — *John Wilkerson*