

mean that care for residents is better,” Edelman’s comments state.

Bentley contends F-tags are not a measure of quality of care. “What they measure is compliance with the regulation,” she said.

The patient advocate comments also took issue with CMS’ classification of certain scenarios in which infection is found in nursing homes. Edelman said it is unclear why the agency would consider some situations harmful that in

fact seem appropriate for classification as immediate jeopardy.

AHCA also commented that CMS is providing guidance that is reasonable for hospitals, but not nursing homes, an especially ill-suited piece of guidance during a time when nursing homes are encouraged to implement culture change so patients feel at home. “We’re going to have to strike a balance between infection control and culture change,” Bentley said.

## Quick Takes

### FDA CONSIDERS RECOMMENDATIONS TO WORK WITH CMS ON DIAGNOSTICS

FDA officials say the agency will “explore ways” to work with CMS to clarify their respective regulatory roles in regulating genomics-based diagnostic products, following a White House panel’s call for better collaboration between the two agencies. A new FDA working group hopes to release guidance on the co-development of diagnostics and drugs in 2009, but the officials say a separate guide on the regulation of automated clinical decision support systems “needs further internal discussion between centers in FDA and other organizations in HHS.”

A Sept. 15 report by the President’s Council of Advisors on Science and Technology identifies obstacles to personalized medicine development and issues recommendations to several agencies, including FDA, on how to advance research.

HHS is still evaluating issues PCAST identifies, say Lawrence Lesko, director of FDA’s Office of Clinical Pharmacology, and Associate Director for Genomics Issam Zineh. “It’s useful to act, but it’s more important to act appropriately and consider all stakeholders,” they write in an e-mail.

The agency recently appointed Zineh as its point person for policy matters and scientific and clinical issues related to genomics applications. He will work with other FDA officers and centers, an FDA press release states.

The White House panel found FDA has made progress defining its regulatory approach to personalized medicine, but that regulatory guidance remains ambiguous or incomplete in several areas. For example, PCAST recommended FDA and CMS clarify requirements and eliminate redundant requirements.

“This is a thoughtful and useful recommendation that many in HHS/FDA/CMS have taken notice of,” Lesko and Zineh state. “More time is needed to give consideration to the best way forward though since the PCAST report is so new.”

PCAST also called for FDA to issue guidance that clarifies its regulatory approach to co-development of diagnostics and drugs. The guidelines should specify how FDA determines when labeling of a therapeutic product should incorporate information on related diagnostic tests. The agency should also establish circumstances for determining when to either recommend or require that patients take diagnostics before receiving treatment, the panel recommended.

Lesko and Zineh say a draft guidance on the subject, to

be released in 2009, is a priority for a new working group. They say it is too early to discuss plans for public meetings or a timeline.

PCAST also urged FDA to issue guidance concerning the regulation of automated clinical decision support systems.

“This topic needs further internal discussion between centers in FDA and other organizations in HHS,” Lesko and Zineh state.

PCAST said that when FDA issues its final guidance on in vitro diagnostic multivariate index assay tests, the agency should clarify its definition of risk in light of the intended IVDMA use, provide illustrative examples distinguishing products that will be subject to full premarket approval review from those that will not, and provide adequate transition time for any new requirements.

PCAST also urged Congress to fund Reagan-Udall and said its board should be expanded to include representatives from venture capital firms and small companies involved in genomics-based diagnostic development.

The FDA Amendments Act required the Reagan-Udall foundation’s creation, but the foundation hit a few setbacks after appropriators cut off the federal funding. Reagan-Udall was envisioned as an extension of FDA’s Critical Path program. — *FDA Week*

### CHRONIC CARE COORDINATION COULD BE HEALTH REFORM OFFSET

Lawmakers planning to reintroduce the Independence at Home Act during the 111<sup>th</sup> Congress are considering tacking it onto an SCHIP reauthorization bill that congressional leadership has said is a necessity to pass, sources tell *Inside CMS*. The legislative measure to institute chronic care coordination for Medicare beneficiaries at their homes received bipartisan support when first introduced as it is one of few health-related proposals with a savings built in, but a family physicians group wants to see the bill tweaked.

If the bill is not added to legislation reauthorizing the State Children’s Health Insurance Program (SCHIP), Jim Pyles, a health attorney who helped draft the measure, said it could be included as a partial offset for broader health reform legislation. “Whether we do comprehensive reform or incremental health reform, we should at least do this,” Pyles said of the general consensus among those supporting the bill.

The act will be first reintroduced as stand-alone legisla-

tion, Pyles said. “The Independence at Home Act is still the only proposal I see out there that would use proven models to generate immediate savings,” he said.

The act, introduced by Sen. Ron Wyden (D-OR) and Rep. Ed Markey (D-MA), would establish a multi-state demonstration program for coordinated care aimed at providing medical services at home for the beneficiaries who consume the majority of the Medicare budget. A caveat in the legislation requires that providers participating must save a minimum of 5 percent annually compared to what would have otherwise been spent by Medicare. If that savings is not realized, the Independence at Home organization must refund any payments. Savings exceeding the 5 percent minimum would be split 80 percent to 20 percent between the IAH organization and Medicare, respectively. (see *Inside CMS*, Sept. 18).

The American Academy of Family Physicians (AAFP) took issue with the language regarding nurse practitioners, claiming it would give rise to competition between nurse practitioners and physicians. AAFP President Ted Epperly said the association thinks the Independence at Home Act is overall a “marvelous” piece of legislation, but it needs a few tweaks to part of the language.

“The reason we came out against it wasn’t because it wasn’t a good idea ... but we felt it didn’t effectively distinguish between the role of the physician and that of the non-providers,” Epperly said.

The specification in the Independence at Home Act that physicians or nurse practitioners can coordinate a beneficiary’s health care treatment would give rise to competition between the two, Epperly said. He suggests language explaining “a collaborative team approach” between nurse practitioner and physician. “It’s not a control issue as much as it is a quality issue,” Epperly said.

AAFP supports the overall idea of chronic care coordination, but Epperly said the group would communicate concerns about the nurse practitioner portion and lobby for a change. But Wyden worked closely with nurse practitioners when developing the bill, Pyles said, and that is language unlikely to change.

It may be that AAFP does not understand the provision,

he said, explaining that “it does not change existing law.” Some states already allow nurse practitioners to act in the provider role in certain situations. The Independence at Home Act maintains the status quo, Pyles said, by continuing to allow nurse practitioners to provide and direct the proposed care teams if states already allow such care.

Pyles also suggested AAFP consider that savings realized through the program could possibly provide additional funding for preventative care and primary care physicians who treat the less ill.

## **CMS ISSUES FINAL MEDICAID COST-SHARING RULE WITH FEW CHANGES**

Medicaid provisions in the Deficit Reduction Act of 2005 are now implemented in a final CMS rule unveiled Nov. 19 that provides states flexibility to require cost-sharing for certain beneficiaries, non-emergency services in hospital emergency rooms and non-preferred drugs. The final rule limits cost-sharing for individuals and families earning below 100 percent of the federal poverty level (FPL).

The final rule, scheduled to be published in the *Federal Register* Nov. 25 with an effective date 60 days later, contains no major changes from the proposed rule issued in February that formalized the DRA and direction CMS issued in June 2006 in a letter to state Medicaid directors (see *Inside CMS*, March 6). Ann Kohler, director of health services for the American Public Human Services Association, said the rule does limit what states can charge for some populations, but maintains states’ flexibility for charging other portions of the Medicaid population.

There had been concern that these sections of DRA and the rule would limit access to care for some Medicaid populations or increase cost-sharing unfairly. Kohler, however, said that isn’t the case given the states’ flexibility under the regulations. “Really, no state has taken this up,” Kohler said, adding any negative impact or decline in access to care has “been very, very limited.”

In February, CMS issued a second proposed rule providing state flexibility for Medicaid benefit packages, for which the agency said it would respond to comments in subsequent rulemaking.

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## **CMS UNAWARE DOCS CAN SECURELY E-PRESCRIBE . . . continued from page 23**

ties will begin being assessed — to avoid the fines for not participating.

To receive the e-prescribing bonus, the total charges reported using the specified denominator codes must make up at least 10 percent of a provider’s overall Part B charges. CMS officials explained during the provider forum that hospital emergency department codes are not on

the e-prescribing denominator, therefore physicians who exclusively bill using those codes could not report any measure — a situation similar to that of the physicians exclusively billing for house calls. During the forum, CMS said the hardship exemption was developed for the HHS secretary to grant because the agency is “quite cognizant in terms of the fairness element here.”