As the Senate and the House on March 17 passed their respective budget resolutions for fiscal 2006, it’s clear that the GOP congressional majority is hewing to the White House tack of avoiding new major changes in Medicare, including payment reductions to laboratories and other providers. The possibility of provider cuts, if not off the table altogether, appears much less likely at this stage than many had previously thought (National Intelligence Report, 26, 9/Feb. 21, ’05, pp. 1, 3-6).

But in a major setback for the President and GOP leaders, the Senate, in passing its $2.6 trillion budget (S. Con. Res. 18) by a vote of 51-49, killed cuts in federal Medicaid spending, education, and other domestic programs that the Senate Budget Committee had earlier approved along strictly partisan lines. The committee’s plan envisioned $14 billion in Medicaid cuts.

The Medicaid reprieve came in an amendment offered by Gordon Smith (R-OR). Six Republicans joined Smith, The Medicaid reprieve came in an amendment offered by Gordon Smith (R-OR). Six Republicans joined Smith,

**Medicare Prepares For Contractor Changes**

Since Medicare began in 1965, it has been required by law to contract with health insurance companies to carry out claims processing and related administrative functions. This year, in accord with the Medicare Modernization Act of 2003, Medicare will begin to change all its claims processing contracts, introducing competition and performance incentives for new entities called Medicare Administrative Contractors (MACs), which may include companies other than health insurers.

On February 22 the Centers for Medicare & Medicaid Services released a map showing how it will divide the U.S. into 15 primary MAC jurisdictions for combined Medicare Part A and B claims processing. The primary MACs will replace 51 Part A intermediaries and Part B carriers that serve overlapping jurisdictions. CMS also will establish specialty MACs for home health and hospice providers as well as another four for durable medical equipment (DME) suppliers.

By law Medicare must switch to the MAC contract system by 2011, but CMS aims to accomplish this by 2009. It will begin with a competition for four new DME MACs to replace existing DME regional carriers (DMERCs). CMS held a town hall meeting on this procurement on February 25 and plans to issue a request-for-proposals this month.
Budget Action Spares Medicare, from p. 1

all 44 Democratic senators, and Vermont independent Jim Jeffords in voting for it. Senators on both sides of the political aisle have acknowledged that home-state governors, increasingly strapped to keep up with Medicaid needs, have lobbied them hard against cuts in the federal share.

But Medicaid cuts could resurface in a conference committee to resolve differences between the Senate and the House budgets. The House’s similar $2.6 trillion version, which passed 218-214, includes cuts of $20 billion in federal Medicaid spending over the next five years. On defense spending, the two budgets are virtually the same. In terms of tax cuts, the House approved $106 billion over the next five years (of which $45 billion could not be axed by the Senate) vs. the Senate’s $134 billion.

The total savings in the two plans are far apart, however. The House version calls for $69 billion in spending cuts over the next five years, while the Senate plan, with the Medicaid cuts removed, calls for $18 billion in cuts over the same period. The differences raise the prospect of a major confrontation between the House and the Senate. If they cannot agree, there will be no final budget, as happened last year.

The budget resolution sets broad tax and spending targets and instructs individual committees to write legislation to achieve these goals. But it’s left to the individual committees to determine the impact on specific programs and tax laws. Under rules of the Congress, a final budget resolution approved by the House and the Senate shields the legislation from a Senate filibuster and it can pass with only a simple majority. Should Congress pass a budget, the measure does not have to be signed by the President and does not have the force of law. Bills passed by individual committees would be rolled into a reconciliation package subject to a straight up-or-down vote.

Boost Sought For Healthcare IT

Tucked into the Senate budget is a provision for a reserve fund for health information technology and pay-for-performance initiatives. It would allow additional funding of an unspecified sum if the Finance or HELP Committee reports a bill or joint resolution with an amendment or conference report that provides incentives or other support for adoption of modern IT to improve healthcare quality and for performance-based payments based on accepted clinical performance measures of quality.

The reserve fund would only be available if it would not increase the deficit in fiscal years 2006 through 2010. So, the technology and incentives would have to save at least as much as they cost, in fairly short order.

Are Physicians In For Another Short-Term Fee Fix?

That’s likely, say political analysts who don’t expect Congress to overhaul this year the statutory formula used to update Medicare Part B fees for pathology and other physician services. Absent legislative intervention, the formula is scheduled to trigger physician fee reductions as of January 1, 2006.

Legislation to revamp the fee update formula has languished on Capitol Hill, despite widespread dissatisfaction with the sustainable growth rate (SGR) factor used.
To prevent physician fee cuts of 4.5% in 2004 and 3.3% in 2005, Congress approved a 1.5% increase for each of these years, as part of the Medicare Modernization Act of 2003.

During a March 15 hearing on pay-for-performance initiatives, Ways & Means health subcommittee chairwoman Nancy Johnson (R-CT) mentioned the possibility of a one-year fix to block fee reductions in 2006 and grant a 1.5% increase instead.

Johnson said she will consider ways to integrate quality incentives into any potential new Medicare physician payment structure. She acknowledged that she has concerns about attempting this integration before adequate universal technology to collect clinical data on which to base the quality standards is in place. Clinical laboratory interests advocate waiting until a standard format, such as LOINC (Logical Observations: Identifiers, Names, Codes), is in place.

**Hill Health Committee Leaders In Place, New Face on House Side**

As expected, Georgia Republican Rep. Nathan Deal has become chairman of the House Energy & Commerce health subcommittee, replacing Florida GOP Rep. Michael Bilirakis (NIR, 26, 7/Jan 24, ‘05, p. 6). Bilirakis, who remains on the subcommittee, is considered friendly to the clinical laboratory industry. As chairman last fall, he spiked a proposed $5 Medicare claims processing fee.

Deal is best known for his work on immigration reform in 1996. He has several times won the Spirit of Enterprise Award from the U.S. Chamber of Commerce and has received the Guardian of Seniors’ Rights Award from the 60 Plus Association, which considers itself a conservative alternative to AARP.

Health-related committee and subcommittee assignments are now in place for the 109th Congress. Below are the GOP chairmen and the ranking Democrats.
Billing consultants and trade associations are advising clinical laboratories to continue billing for certain services that Medicare’s old paper-based manuals authorized, but its new Internet-only manuals do not. Meanwhile, CMS officials are working to develop a clear position on the matter.

At issue are discrepancies in two policies that were noted by Christopher Young, president of Phoenix-based Laboratory Management Support Services, and described in our January 10, 2005 issue (p. 5):

- Can labs bill Medicare for specimen collection at nursing homes even if on-duty personnel are qualified to do so? The old manual says you can; the Internet-only manual says you can’t.
- Can pathologists order additional tests they deem necessary when reading a tissue sample? The old manual included this as an exception to the general rule that only the treating physician can order lab tests; it’s missing from the Internet-only manual.

The NIR article noted that Richard Lawlor of CMS told an open-door forum that the paper and Internet manuals should substantively agree, but if not, the Internet manuals take precedence. Lawlor is director of the outreach and speech writing group in the CMS office of external affairs.

Some pathologists who read the article contacted the College of American Pathologists for guidance on whether they should continue ordering the additional tests under the exception that has been in the paper manual since 2001. CAP’s assistant director of practice management, George Roman, advised them to continue ordering the tests because a provision at www.cms.hhs.gov/manuals says that during the transition from paper- to Internet-based manuals, “you should check both sets of manuals for current policy and procedures.”

In a letter to NIR, consultant Dennis Padget, MBA, CPA, FHFMA, who heads DL Padget Enterprises (Simpsonville, KY), said that in January 1992 HCFA (now CMS) told carriers not to pay for routine specimen collection if it is within the legal scope of practice of the nursing home personnel to perform venipuncture. Under heavy fire from nursing home and lab providers, the agency reversed this policy in December 1992 and declared that labs could charge a specimen collection fee “regardless of the qualifications of nursing home personnel to collect specimens.” The policy reversal was noted in sections in the carrier and intermediary manuals, but not at other critical points in the paper-based system. Through an apparent oversight, CMS mistakenly carried forward the obsolete, erroneous provisions into the Internet-only manuals.

Padget suggests that “after consulting with legal counsel,” labs should continue charging for nursing home specimen collection. “Failure to charge such fees on current claims may bar recovery when CMS discovers and corrects the Internet-only manual policy statement error, assuming carriers are even denying the charges at present.”

The exception allowing pathologists to order additional tests they deem necessary to read a tissue sample was unintentionally omitted, in Padget’s view. “I believe one has to conclude from the available evidence that someone at CMS simply slipped up.” Pathologists should still order such tests as needed, he concluded, because:
• The general requirement that only treating physicians may order tests is also missing from the Internet-only manual, not just the provisions specific to pathologists.
• The underlying regulation defines treating physicians to include those who furnish a consultation, such as pathologists.
• Stark II physician self-referral rules protect “a pathologist’s right to self-order diagnostic tests and procedures when necessary to finalize the examination of a specimen that’s been referred by an independent physician.”

In response, Young believes the general “treating physician” requirement has not been omitted, but was moved to the Internet-only version of the Medicare Benefits Policy Manual. He agreed with Padget, however, on the importance of continuing to bill for specimen collection and for additional tests. “I’m not recommending that any lab change its practices in these two instances, and I’m not aware of anybody getting any claims denials,” he told NIR via e-mail.

Changes Ahead In Billing Medicare For Blood Charges

Providers paid under Medicare’s outpatient prospective payment system (bill types 12X and 13X) should take note of new billing policies when they report charges for blood and blood products for services furnished on or after July 1 of this year. These policies are found in a new section that the Centers for Medicare & Medicaid Services has added to Chapter 4 of the Medicare Claims Processing Manual (Change Request 3681, March 4, 2005).

The new section 231 provides billing instructions for a new HCPCS modifier, BL, to use when purchasing blood or blood products from a community blood bank, or when assessing charges for blood or blood products collected by the provider’s own blood bank, if the charges exceed their blood processing and storage costs.

The provider must report these charges separately from its processing and storage service charges by using Revenue Code series 038X with the line item date of service, the number of units transfused, the appropriate blood product HCPCS code, and the new BL modifier. The processing and storage service charges must be reported on a separate line, using Revenue Code 0390 or 0399, also with the number of units, the appropriate HCPCS code, and the BL modifier. The Outpatient Code Editor used by Medicare contractors will return a claim for blood or blood products unless it is accompanied by a claim for storage services with a matching date of service, number of units, HCPCS code, and BL modifier.

CMS notes that the annual blood deductible applies only to the purchase of whole blood or packed red cells from a community blood bank or if the provider assesses a charge for blood collected in its own blood bank that exceeds the provider’s blood processing and storage charges.

The new section 231 describes billing policies for autologous blood (including salvaged blood), as well as directed donor blood, split units of blood, irradiation of blood products, frozen and thawed blood and blood products, unused blood, transfusion services, andpheresis and apheresis services. The new section also addresses edits under Medicare’s Correct Coding Initiative. The CMS contact is Marina Kushnirova at mkushnirova@cms.hhs.gov.
with contracts awarded by December. In fiscal 2004, the existing DMERCs processed over 68 million claims from suppliers of DME, orthotics, and prosthetics amounting to Medicare benefit payouts in excess of $9,074 million, according to CMS data.

For the primary A/B MACs, CMS held a town hall meeting on March 16 and plans to issue a request-for-proposals in September, hold a pre-proposal conference shortly thereafter, and award the first contract by June 2006.

According to the statement of work, CMS will require the new contractors to consolidate the local coverage determinations of existing contractors. Most MACs will cover areas that previously involved two or three Part B carriers and two to six intermediaries. CMS will not require primary A/B MACs to offer employment to staff of intermediaries and carriers that don’t win MAC contracts. 📊

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### The primary A/B MAC jurisdictions recently announced by CMS are:

<table>
<thead>
<tr>
<th>No.</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>American Samoa, California, Guam, Hawaii, Nevada, Northern Mariana Islands</td>
</tr>
<tr>
<td>2</td>
<td>Alaska, Idaho, Oregon, Washington</td>
</tr>
<tr>
<td>3</td>
<td>Arizona, Montana, North Dakota, South Dakota, Utah, Wyoming</td>
</tr>
<tr>
<td>4</td>
<td>Colorado, New Mexico, Oklahoma, Texas</td>
</tr>
<tr>
<td>5</td>
<td>Iowa, Kansas, Missouri, Nebraska</td>
</tr>
<tr>
<td>6</td>
<td>Illinois, Minnesota, Wisconsin</td>
</tr>
<tr>
<td>7</td>
<td>Arkansas, Louisiana, Mississippi</td>
</tr>
<tr>
<td>8</td>
<td>Indiana, Michigan</td>
</tr>
<tr>
<td>9</td>
<td>Florida, Puerto Rico, U.S. Virgin Islands</td>
</tr>
<tr>
<td>10</td>
<td>Alabama, Georgia, Tennessee</td>
</tr>
<tr>
<td>11</td>
<td>North Carolina, South Carolina, Virginia West Virginia</td>
</tr>
<tr>
<td>12</td>
<td>Delaware, District of Columbia, Maryland New Jersey, Pennsylvania</td>
</tr>
<tr>
<td>13</td>
<td>Connecticut, New York</td>
</tr>
<tr>
<td>14</td>
<td>Maine, Massachusetts, New Hampshire, Rhode Island, Vermont</td>
</tr>
<tr>
<td>15</td>
<td>Kentucky, Ohio</td>
</tr>
</tbody>
</table>

CMS spelled out the timetable below to transition the full fee-for-service workload to MACs by October 2009:

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Workload Being Competed</th>
<th>RFP Issuance Date</th>
<th>Award Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start-Up</td>
<td>DME MACs</td>
<td>March 2005</td>
<td>Dec. 2005</td>
</tr>
<tr>
<td>Cycle One</td>
<td>Jurisdictions 1, 2, 4, 5, 7, 12, 13</td>
<td>Sept. 2006</td>
<td>Sept. 2007</td>
</tr>
<tr>
<td>Cycle Two</td>
<td>Jurisdictions 6, 8, 9, 10,11, 14, 15 and the Home Health/Hospice MACs</td>
<td>Sept. 2007</td>
<td>Sept. 2008</td>
</tr>
</tbody>
</table>

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### ‘Date Of Service’ Defined For Certain Lab Testing Situations

Under the negotiated rulemaking that developed the laboratory national coverage decisions, the Centers for Medicare & Medicaid Services specified that the date of service for stored specimens is the date of retrieval from the archives. But this led to questions about how long a specimen had to be stored to be considered “archived.” In a proposed rule (Federal Register, December 23, 2003), the agency suggested a time frame of more than 30 days.
Now, in a final notice issued February 25, CMS has adopted the standard of more than 30 calendar days. The agency also changed its policy on the date of service when the specimen collection spans more than 24 hours. Previously, that date was the date when the collection began. Now, CMS specifies the collection end-date as the date of service, noting that it is common practice in the lab community to use the end-date.

In the final notice, CMS also finalized proposals for three separate processes to request changes to the lab national coverage decisions (NCDs):
- An abbreviated process for handling requested coding changes that flow from the “covered indications” narrative.
- A streamlined process for clerical coding changes, such as when ICD-9-CM diagnosis codes or CPT procedure codes are updated.
- Reserving the normal evidence-based NCD process for substantive changes.

**FDA Yanks Guideline On Blood Computer Systems**

The Food & Drug Administration has withdrawn its draft guideline for validation of blood establishment computer systems that was issued on September 28, 1993. The agency is revising the guidance and plans to release a new draft for public comment “in the future,” according to a notice in the March 9 Federal Register.

The FDA says the document “no longer reflects all of FDA’s current considerations on a guidance to assist manufacturers of blood and blood components, including blood banks, plasmapheresis centers, and transfusion services, in developing a computerized system validation program.”

**CODING ADVISORY**

Two ICD-9-CM diagnosis codes have been added as codes covered under Medicare’s national coverage decision (NCD) for tumor antigen by immunoassay CA 19-9. The codes are 156.0 (Malignant neoplasm of the gallbladder) and 156.2 (Malignant neoplasm of the Ampulla of Vater). The Centers for Medicare & Medicaid Services determined that these codes flow from the existing narrative for conditions for which CA 19-9 is reasonable and necessary. The change was sparked by a December 22, 2004 request from Debbie Beedlow of Hematology & Oncology Consultants (Orlando, FL) regarding the code for Malignant neoplasm of the Ampulla of Vater.

Separately, CMS plans to remove ICD-9 code 784.69 (Other symbolic dysfunction) as a code covered under the hepatitis panel NCD, on grounds that it does not flow from the existing narrative for conditions for which the panel is reasonable and necessary. This change stems from an analysis, begun by the agency on December 23, 2004, of the ICD-9 codes covered for the panel.

**Correction:** In our February 7, 2005 issue (p. 5), we incorrectly reported that a California Medicaid contracting initiative would award contracts to independent labs only if they agree to a 20% cut in reimbursement. Currently, the state pays 20% below Medicare rates for most tests, even less for others. A state official told us that under the contracts the state plans to award, overall reimbursement will increase slightly.
Medicare Tweaks Secondary Payer Policy

The Centers for Medicare & Medicaid Services has told local Medicare contractors to instruct hospital and independent laboratories that they may use any Medicare secondary payer (MSP) information they have already collected and retained when billing for reference testing performed without a face-to-face encounter with the beneficiary. Where a face-to-face encounter is involved, these labs must collect this information from the beneficiary when billing for their services (Change Request 3729, March 4, 2005).

CMS said this clarification should have been part of a previous Change Request (#3267, July 16, 2004), which in turn clarified CR 3064 (NIR, 25, 21/Sep 13, ‘04, p. 7; 25, 10/Mar 8, ‘04, p. 3). There is a link in the MSP Manual to the Medicare Claims Processing Manual stating this clarification, the agency noted; however, the link is directed to carriers. Since the clarification applies to fiscal intermediaries as well, CMS is adding appropriate language to the MSP Manual section (20.1.1).

Under an MSP policy change required by Section 943 of the Medicare Modernization Act of 2003, Medicare must treat hospital reference testing the same as independent lab reference work that does not involve a face-to-face encounter with the beneficiary. Accordingly, CMS has said that since it will not require independent labs to collect MSP information in order to bill Medicare, absent a face-to-face encounter, it will not require hospital reference labs to do so. ▲

GOP Wants Hands Off Medicare In ’05

Though the national debate over Social Security is capturing headlines as President Bush and Congress tangle over assuring the program’s future solvency, what has largely escaped public notice is the fact that Medicare is in far worse fiscal shape and its cure far less certain.

What’s increasingly clear to Washington insiders is that the Bush Administration and GOP congressional leaders have decided to keep hands off Medicare this year, fearing that debate over its fiscal health could open a political “can of worms” surrounding the 2003 Medicare Modernization Act and the continuing controversy over the higher cost estimates for the new prescription drug benefit, debuting in 2006.

GOP leaders are also aware that any steps to restrain Medicare’s growth now could put them in even more political peril than they already face over Social Security.