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Pricing Proposed for New 2011 Medicare Lab Codes

CMS also invited input on reconsideration requests for five codes on the current lab fee schedule. For one contested code, 86352 for cellular function, ASM and CAP advised using the gapfill method in conjunction with microcosting data from the manufacturer.

Leading scientific societies and national clinical laboratory and pathology groups are among those who responded to the call for comment on how to set payment rates for CPT and HCPCS codes to be added to the Part B lab fee schedule, as of Jan. 1, 2011.

The Centers for Medicare and Medicaid Services (CMS) opened the comment period at a July 22 public meeting (*NIR 10, 14/July 23, p. 1*). The agency sought advice from stakeholders on whether to use the crosswalk method or the gapfill method to price:

- 11 new CPT codes in drug testing, chemistry, hematology and coagulation, immunology, transfusion medicine, and microbiology, and
- Five HCPCS G codes that CMS has priced internally.

The table on pages 2 and 3 presents pricing recommendations from five leading groups contacted by *NIR*: the American Association for Clinical Chemistry (AACC), American Clinical Laboratory Association (ACLA), American Society for Clinical Pathology (ASCP), American

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CMS Proposes Requiring Physician Signature on Lab Test Requisitions

Clinical laboratories will face major operational problems if the Centers for Medicare and Medicaid Services (CMS) reverses longstanding Medicare policy and goes ahead with its proposal to require the signature of a physician or a nonphysician practitioner (NPP) on all requisitions for tests paid via the Part B lab fee schedule.

The proposal, announced in a July 13 proposed rule for the 2011 Medicare physician fee schedule, drew swift oppositions from the Clinical Laboratory Coalition, which includes 10 major lab associations. CMS invites comments by Aug. 24 and said it will address them in the final physician fee schedule that it expects to publish in November.

Currently, under a rule finalized in 2001 and resulting from a congressionally mandated lab-negotiated rulemaking and reiterated by CMS in subsequent manual issuances, a physician's signature is one way to document that the treating doctor ordered the service, but it is not the only permissible way and should not be required as long as such documentation exists in an alternate form. For example,

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Medicare Pricing for New 2011 Lab Fee Schedule Codes:
Recommendations of Five Leading Organizations

*Code/Descriptor**	*Recommended Payment Method*	*Current National Fee Cap*
DRUG TESTING		
801XX, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure (this CPT code takes the place of the HCPCS code G0430)	**AACC**: Crosswalk to **80101**, Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class	$19.72
	ACLA, ASCP, CAP: Crosswalk to **G0430**, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure	$20.83
CHEMISTRY		
829XX, Gastric acid analysis, includes pH if performed, each specimen	**AACC, ACLA, ASCP, CAP**: Crosswalk to **82928**, Gastric acid, free or total, each specimen	$9.38
838XX, Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity	**CAP**: Gapfill, based on the manufacturer's microcosting analysis	N/A
841XX, Placental alpha microglobulin-1 (PAMG-1), cervicovaginal secretion, qualitative	**AACC, ACLA, ASCP, ASM, CAP**: Crosswalk to **82731**, Fetal fibronectin, cervicovaginal secretions, semiquantitative	$92.26
HEMATOLOGY AND COAGULATION		
855XX, Phospholipid neutralization; hexagonal phospholipid)	**ACLA, ASCP, CAP**: Crosswalk to **85597**, Platelet neutralization	$25.75
IMMUNOLOGY		
864XX, Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension	**AACC: 86480**, Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response, **plus 86359**, T-cells, total count	$88.77 + $54.03 = $142.80
	ACLA, ASCP, ASM, CAP: **86480**, Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response	$88.77
TRANSFUSION MEDICINE		
869XX, Blood typing; antigen testing of donor blood using reagent serum, each antigen test	**ACLA, ASCP, CAP**: **86903**, Blood typing; antigen screening for compatible blood unit using reagent serum, per unit screened	$13.52
MICROBIOLOGY		
875XX1, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, reverse transcription and amplified probe technique, each type or subtype	**AACC, ACLA, ASCP, ASM, CAP**: **87798**, Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism, **plus 83902**, Molecular diagnostics; reverse transcription	$50.27 + $20.33 = $70.60
875XX2, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, reverse transcription and amplified probe technique, first two types or subtypes	**AACC**: Crosswalk to **87798 x 2**, Infectious agent detection by nucleic acid, not otherwise specified; amplified probe technique, each organism, **plus 83902 x 2**, Molecular diagnostics; reverse transcription	$88.77 x 2 = $176.54 + $20.33 x 2 = $40.66
	ACLA, ASCP, ASM, CAP: Crosswalk to **87801**, Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique **plus 83902**, Molecular diagnostics; reverse transcription	$100.54 + $20.33 = $120.87

CODE/DESCRIPTOR*	RECOMMENDED PAYMENT METHOD	CURRENT NATIONAL FEE CAP
875XX3, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or subtype beyond two (List separately in addition to code for primary procedure)	**AACC**: Crosswalk to **87798 plus 83902**	$50.27 + $20.33 = $70.60
	ACLA, ASCP, ASM, CAP: Crosswalk to **83901**, Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond two (List separately in addition to code for primary procedure), **plus 83896**, Molecular diagnostics; nucleic acid probe, each	$24.01 + $5.74 = $29.75
879XX, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion)	**AACC, ACLA, ASCP, ASM, CAP**: Crosswalk to **87901**, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease	$368.73
HCPCS CODES		
G0432, Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: EIA HIV-1/HIV-2 screen	**AACC, ACLA, ASCP, ASM**: Crosswalk to **86703**, Antibody, HIV-1 and HIV-2, single assay	$19.65
G0433, Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: ELISA HIV-1/ HIV-2 screen	**AACC, ACLA, ASCP, ASM**: Crosswalk to **86703**, Antibody, HIV-1 and HIV-2, single assay	$375.88
G0435, Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening. Short descriptor: Oral HIV-1/ HIV-2 screen	**AACC, ACLA, ASCP, ASM**: Crosswalk to **86703**, Antibody, HIV-1 and HIV-2, single assay	$19.65

CPT codes © American Medical Association. The last two digits to be finalized; for microbiology, the digits to be supplied are the fourth and fifth. Acronyms: American Association for Clinical Chemistry (AACC), American Clinical Laboratory Association (ACLA), American Society for Clinical Pathology (ASCP), American Society for Microbiology (ASM), and the College of American Pathologists (CAP).

CMS Finalizes Changes in ESRD Lab Test Payments

For renal dialysis facilities and clinical laboratories that serve them, major changes are in store next year under a final rule implementing Medicare's transition to a new prospective payment system for outpatient dialysis services to beneficiaries with end-stage renal disease (ESRD). The changeover is required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Under the new system, the current split between lab testing services paid under the composite rate and services separately billable to Part B will end, and as of Jan. 1, 2011, reimbursement for these tests will be rolled into a single bundled ESRD payment. But the furnishing of blood, blood products, and blood supplies in connection with transfusions will remain separately billable when administered in an ESRD facility.

Details of the new ESRD payment system were released July 26 by the Centers for Medicare and Medicaid Services (CMS). The law requires CMS to phase in the system over four years, but facilities may choose to be paid entirely under prospective payment starting in 2011 or to be paid under blended *Continued on p. 4*

ESRD Lab Test Payments, *from p. 3*

rates during the transition. Providers have until Nov. 1 of this year to decide.

The final rule presents a list of clinical laboratory services subject to ESRD bundled payment (*see table*). It is drawn from previous claims data on tests frequently billed for ESRD beneficiaries, CMS said, adding that it should not be considered all-inclusive and may be expanded or otherwise modified based on future claims analysis as the program rolls out.

ESRD Stats

Facilities affected: 600 hospital-based and 4,300 freestanding ESRD facilities furnishing outpatient maintenance dialysis services.
Beneficiaries served: Nearly 330,000 Medicare patients.
Total Medicare payments for services: $9.2 billion, including dialysis and related services. About $5.7 billion, or 62 percent was paid under the composite rate, while about $3.5 billion or, 38 percent, was paid for separately billable services.

Source: CMS. Data from 2007, the base year used to determine the new ESRD bundled payment rates.

The base payment rate per treatment in 2011 is $229.63, up from the previously proposed rate of $198.64 (*NIR 10, 2/Jan. 25, p. 1*). The rate represents what Medicare will pay for all services in the bundle prior to adjustments for case mix and the wage index, including former composite rate and separately billable services.

Beneficiaries are liable for 20 percent of the ESRD bundled payment, including applicable case mix and facility-level adjustments and outlier payments. Those served by facilities going through the four-year transition are liable for 20 percent of the blended amount. Although clinical lab services are not currently subject to coinsurance, lab services that are bundled are subject to 20 percent coinsurance as part of the bundled set of renal dialysis services. This is also true for drugs being bundled that are now payable under Medicare's prescription drug program and subject to a separate coinsurance structure.

In the final rule, CMS backed off from its earlier proposal, assailed by lab groups and others, to include in the bundled payment—in addition to lab tests separately billable as of Dec. 31, 2010—lab tests that are ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients and are billed by independent labs. Opponents said that MCP physicians are often the patient's primary care physician and often order tests unrelated to ESRD. The agency said it recognized this and has developed billing modifiers to allow for separate payment where the lab testing is not ESRD-related.

Highlights of the Final Rule

The rule for the new payment system:

- ❑ Creates a home or self-care dialysis training payment adjustment specifically directed to patients trained by facilities certified to provide home dialysis training.
- ❑ Finalizes payment adjustments for dialysis treatments furnished to adults for patient age, body surface area, body mass index, onset of dialysis, and certain comorbidities, but does not finalize adjustments for sex, race, or ethnicity.
- ❑ Finalizes a payment adjustment for dialysis treatments furnished to pediatric patients, based on patient age and dialysis modality, but not comorbidities.
- ❑ Finalizes a definition for renal dialysis services that includes ESRD-related oral-only drugs but postpones bundled payment for them until Jan. 1, 2014.

ESRD Pay for Performance

Along with the final ESRD bundled payment rule, CMS released a proposed rule

establishing a new quality incentive program (QIP) by 2012 that will link dialysis facility payments to performance standards. Significantly, CMS noted, this is the "first pay-for-performance program in a Medicare fee-for-service payment system." Currently, facilities only report on whether they have complied with quality measures. Beginning for services on or after Jan. 1, 2012, facilities that fail to meet the QIP performance standards will see their payments reduced.

When the program debuts, payment will be tied to performance on QIP measures for anemia management and hemodialysis adequacy. These were chosen, CMS said, because they are relevant to the health of the Medicare beneficiary receiving dialysis services, they have been used by dialysis facilities since 2001, and facilities are familiar with them. In addition, these measures are currently collected from dialysis facility claims, relieving the facilities of the need to report them separately. CMS has been collecting such data since 2001.

ESRD-Related Laboratory Tests

CPT/ HCPCS	Short Description	CPT/ HCPCS	Short Description
82040	Assay of serum albumin	84520	Assay of urea nitrogen
82108	Assay of aluminum	84540	Assay of urine/urea-n
82306	Vitamin d, 25 hydroxy	84545	Urea-N clearance test
82310	Assay of calcium	85014	Hematocrit
82330	Assay of calcium, Ionized	85018	Hemoglobin
82374	Assay, blood carbon dioxide	85025	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count
82379	Assay of carnitine	85027	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)
82435	Assay of blood chloride	85041	Automated rbc count923
82565	Assay of creatinine	85044	Manual reticulocyte count
82570	Assay of urine creatinine	85045	Automated reticulocyte count
82575	Creatinine clearance test	85046	Reticyte/hgb concentrate
82607	Vitamin B-12	85048	Automated leukocyte count
82652	Vit d 1, 25-dihydroxy	86704	Hep b core antibody, total
82668	Assay of erythropoietin	86705	Hep b core antibody, igm
82728	Assay of ferritin	86706	Hep b surface antibody
82746	Blood folic acid serum	87040[1]	Blood culture for bacteria
83540	Assay of iron	87070[1]	Culture, bacteria, other
83550	Iron binding test	87071[1]	Culture bacteria aerobic other
83735	Assay of magnesium	87073[1]	Culture bacteria anaerobic
83970	Assay of parathormone	87075[1]	Culture bacteria, except blood
84075	Assay alkaline phosphatase	87076[1]	Culture anaerobe ident, each
84100	Assay of phosphorus	87077[1]	Culture aerobic identify
84132	Assay of serum potassium	87081[1]	Culture screen only
84134	Assay of prealbumin	87340	Hepatitis b surface ag, eia
84155	Assay of protein, serum	G0306	CBC/diff wbc w/o platelet
84295	Assay of serum sodium	G0307	CBC without platelet
84466	Assay of transferrin		

[1] *Only ESRD-related when testing is related to the dialysis access site.*
Source: ESRD Final Rule, Appendix Table F.

Physician Signature, *from p. 1*

the physician may document the ordering of specific services and their medical necessity in the patient's medical record.

CMS says the approach it is proposing would address concerns raised about the present policy, resulting in a less confusing process and providing a straightforward directive for laboratories to meet. Requiring the signature of a physician or NPP for all requisitions and orders would eliminate "uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature."

Nor would it increase the burden on physicians, CMS says. "It is our understanding that, in most instances, physicians are annotating the patient's medical record with either a signature or an initial (the order), as well as a signature on the paperwork that is provided to the clinical diagnostic laboratory that identifies the test or tests to be performed for a patient (the requisition).

"Further, this policy would make it easier for reference laboratory technicians to know whether a test is appropriately requested, and potential compliance problems would be minimized during the course of a subsequent Medicare audit because a signature would be consistently required."

Problems Posed for Labs

Asked by *NIR* for comment, attorney Robert E. Mazer with Ober/Kaler in Baltimore noted, "CMS says this policy will result in less confusion, but it appears to have created the confusion it attempts to minimize in recognizing a distinction between 'orders' and 'requisitions' for clinical lab tests.

"Complying with this new requirement, if finalized, will be a huge problem for many labs. They won't know what the requirements will be until sometime in November and will then have to have new procedures in place on Jan. 1. This may require them to print new requisitions, if existing ones don't accommodate a physician's signature. It will also require them to educate physicians about this new requirement. It's also unclear how this will impact electronic ordering arrangements. Will an electronic signature be required? If so, will there be specific rules as to what is considered acceptable? Many existing electronic ordering systems cannot accommodate an electronic signature.

"I suspect that labs and physicians will strongly disagree with CMS that this requirement would not increase the burden on physicians. While physicians may initial or sign the medical record entry, it is unlikely they can sign the requisition at the same time. The requisition requires significant patient demographic information and may not be completed until much later—possibly after the physician has left the office to go on hospital rounds.

"Labs will have the unenviable task of getting physicians to comply with this requirement. It will also leave labs in an untenable position when a test sample arrives with an unsigned requisition. If they don't perform the test until they receive a physician signature, the lab specimen may be compromised and the physician may not receive the timely test result that he or she requires to diagnose or treat the patient. But if they do perform the test and aren't able to obtain a signature, then they are at risk of not being paid."

In its recent alert to members, the Clinical Laboratory Management Association said the reversal of Medicare policy "places a burdensome and unnecessary requirement on both labs and physicians, creating a literal blizzard of paperwork, expense and resource commitment for no good reason. If there is no signature on the requisition the lab receives, the tests on the requisition would not be considered medically necessary so the lab would not be able to file a claim for the tests. Correcting this requires that the requisition be faxed, mailed, or delivered by courier back to the physician's office for the signature, a simple phone call would not be sufficient."

AAB Wins Key Court Ruling Against N.Y. State Health Department

For more than 11 years, the American Association of Bioanalysts (AAB) has fought a court battle against the New York State Department of Health, claiming that it was intentionally overcharging clinical laboratories so that it could subsidize its many other research programs that had no relation to covering the necessary costs of regulating clinical labs and blood banks.

According to AAB's complaint, "Lab levies have increased sevenfold on an industry-wide basis from $2.4 million per year in 1984 to more than $17 million per year today."

AAB scored a key victory July 22 when the state's Appellate Division, Third Department, rejected an appeal from the health department and unanimously upheld a lower court's decision, agreeing that the fees charged to labs were "arbitrary and capricious" and that the department's "bald estimates" of the actual costs of lab regulation could not support the fees charged when the department failed to keep accurate, up-to-date financial records or even disclose those documents in support of the cost estimates. Writing for the court, Justice Robert S. Rose noted, "The department's intention to shift as many costs as possible onto clinical labs was further revealed in testimony that the director had once boasted he had been able to transfer 17 percent of the Wadsworth Center's budget to the clinical labs."

AAB commenced the lawsuit when it learned that expenditures were being made from lab fees for salaries of persons whose jobs had nothing to do with the regulation of New York-licensed clinical labs, and in some cases who did not even work for the department. Monies were also used to pay for trips to California and Europe and cars for the New York health commissioner.

AAB's general counsel Jeffrey Sherrin, who both tried the case and successfully argued the appeal, said, "The department abused a program properly established by the legislature, used it as a slush fund, and then tried every maneuver imaginable to hide what it did."

The case now goes back to the department to recalculate the fees that should have been charged to AAB member labs. This should enable labs to recover 75 percent of the money they paid between 1998 and 2006. But noted AAB administrator Mark S. Birenbaum, Ph.D., "All labs will benefit from the fight we have waged," since the department will have to conform its future billings to the court decision. The department has 30 days from the court's ruling to appeal to the state's highest court, which typically limits its caseload to those where legal findings are in sharp dispute.

Pricing Proposed, *from p. 1*

Society for Microbiology (ASM), and the College of American Pathologists (CAP).

Two methods are used to set rates on the lab fee schedule: crosswalk or gapfill. Under the crosswalk method, a new test code is matched to a similar code on the fee schedule and paid at that rate. Payment is the lower of the local fee schedule amount or the national fee cap. Most lab codes are paid at the cap.

The gapfill alternative is used when there is no comparable existing test. In this case, local contractors set the fee for the first year, based on local pricing patterns such as charges for the test, routine discounts, resources needed for the test, and what other payers pay. CMS then taps these local amounts to set a fee cap for following years.

Next Steps in the Fee-Setting Process

CMS typically makes public its tentative fee decisions for new lab codes in September, followed by a two-week period for additional comments. Final fee decisions will be announced in the 2010 Part B lab fee schedule via a program transmittal to local contractors, typically released in November.

Reminder: August is a one-issue month for the *National Intelligence Report.*

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