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Lab, Pathology Groups Propose Pricing For New Lab Codes

CMS will announce its preliminary fee determinations by September 8 and receive additional comments through September 25. The final decisions will be published in the 2006 Medicare lab fee schedule which CMS says will be widely available in November

At a July 18 public forum, the Centers for Medicare & Medicaid Services threw open the door to recommendations on how it should establish pay rates for new CPT lab codes that will be added to the Part B lab fee schedule, effective January 1, 2006.

Speakers at the forum, largely representing leading clinical laboratory and pathology groups and diagnostics manufacturers, were unanimous in calling for use of the crosswalk method to set fees (*see table, p. 2*). Under this method, a new code is matched to an equivalent existing code and its reimbursement rate.

One new code would enable doctors to get reimbursed for A1C testing in their offices with a home-use kit approved by the Food & Drug Administration. The kits provide real-time measurement of A1C levels, physician advocates say, and help clinicians better manage glycemic control in people with diabetes. Proponents at the forum said payment close to the $21 mark (CPT 82985) is needed to cover costs and promote access in primary care.

INSIDE NIR

HHS Plan Hikes Outpatient PPS Rates

Acute care hospitals would get a 3.2% increase in Medicare payments in 2006 for outpatient services, according to a proposed rule released July 18 by the Centers for Medicare & Medicaid Services. Sole community hospitals in rural areas will get an extra 6.6%. Beneficiaries would see lower co-insurance rates. Rates have declined since peaking at 50%, down to 40% and eventually 20%. Payment for the "Welcome to Medicare" physical checkup furnished on an outpatient basis would rise by nearly 7%.

For blood and blood products, Medicare would continue to make separate payments through individual APCs for each product. Pay rates would be based on the same method in the 1994 final rule, using hospital-specific actual or simulated cost-to-charge ratios for blood cost centers to convert hospital charges to costs.

For multiple diagnostic imaging services in the same session, payment for the first procedure would be made in full, but would be reduced by 50% for subsequent procedures in 11 "families," based on modality and contiguous body area. In all, Medicare outpatient spending will increase to $27.5 billion in 2006 from $26.1 billion in FY 2005, says CMS.

New CPT Codes For 2006 Medicare Lab Fee Schedule • *Recommended Crosswalks, Related Fees*

Code	Descriptor	Crosswalk to	Agree	Disagree
CHEMISTRY				
• **8227x**	Fecal occult blood, peroxidase (eg, guaiac); single specimen, (eg, from digital rectal exam)	82270 ($4.54)*	AACC, ACLA, ASCP, CAP, CLMA	
• **8303x**	glycosylated (A1C) by device cleared by FDA for home use	83036 ($13.56)	ACLA, CLMA, Roche; ASCP, CAP, 83036 at 60%	AACC, 82985 ($21.06)
• **8363x**	Lactoferrin, fecal; quantitative	83520 ($18.09)	AACC, ACLA, CAP, CLMA	ASCP, ASM, 87015 ($9.33) + 83520 ($18.09)
• **8369x**	Lipoprotein (a)	83520 ($18.09)	AACC, ACLA	ASCP, CAP, 82172 ($21.65); CLMA 83883 ($19)
• **8370x**	Lipoprotein, blood; electrophoretic separation and quantitation	83715 (deleted & renumbered) ($15.73)	AACC, ACLA, ASCP, CAP, CLMA	
• **8370x**	high resolution fractionation and quantitation of lipoproteins including subclasses when performed (eg, electrophoresis, ultracentrifugation)	83716 (deleted & renumbered) ($34.68)	AACC, ACLA, ASCP, CAP, CLMA	
• **8370x**	quantification of lipoprotein particle numbers and lipoprotein particle subclasses (eg, by nuclear magnetic resonance spectroscopy)	83716 ($34.68) plus 85004 ($9.04)	AACC, ACLA, ASCP, CAP, CLMA, LipoScience	
• **8390x**	amplification of patient nucleic acid, multiplex, first two nucleic acid sequences each	83898 ($23.42) X 2	AACC, ASM; ASCP, CAP, 190% of 83898	ACLA, CLMA, Roche, 83901($23.42) X 2
• **8390x**	lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue)	87015 ($9.33)	AACC, ACLA; ASCP, CAP, 87015 X 2	ASM, 87176 ($8.22) + 87015 ($9.33); CLMA, 83890 ($5.60)
• **8390x**	signal amplification of patient nucleic acid, each nucleic acid sequence	83898 ($23.42)	AACC, ACLA, ASCP, ASM, CAP, Roche	CLMA, 83898 X 140%
• **8390x**	separation and identification by high resolution technique (eg, capillary electrophoresis)	82664 ($48)	AACC, CLMA	ACLA, 84165 ($15.01); ASM, 83903 ($23.42); ASCP, CAP, 83904 ($23.42)
• **8391x**	Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay (OLA), single base chain extension (SBCE), or allele specific primer extension (ASPE)	83905 ($23.42)	AACC, Roche	ACLA, 83904 ($23.42); ASCP, CAP, 83903 ($23.42); ASM, CLMA, Luminex, 83904 ($23.42)
IMMUNOLOGY				
• **8620x**	Cyclic citrullinated peptide (CCP), antibody	83520 ($18.09)	AACC, ACLA	ASCP, CAP, 86039 ($15.60); CLMA, 86148 ($22.44)
• **8635x**	B cells, total count	86064 (deleted & renumbered) ($52.70)	AACC, ACLA, ASCP, ASM, CAP, CLMA	
• **8635x**	Natural killer (NK) cells, total count	86379 (deleted & renumbered) ($52.70)	AACC, ACLA, ASCP, ASM, CAP, CLMA	
• **8636x**	Stem cells (i.e., CD34), total count	86587 (deleted & renumbered) ($52.70)	AACC, ACLA, ASCP, CAP, CLMA	ASM, 86587 ($52.70) + 86361 ($37.41)
• **8648x**	Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response	86353 ($68.49	AACC, CLMA	ASCP, ASM, CAP, 86353 ($68.49) + 83520 ($18.09)
MICROBIOLOGY				
• **8720x**	Smear, primary source with interpretation; complex special stain (eg, trichome, iron hemotoxylin) for ova and parasites	87207 ($8.37)	AACC, ASCP, CAP	ACLA, 88313TC** (or $44.89, cap for 88273); ASM, natl. mean of 88104TC** ($24.20); CLMA, 88313TC
• **8790x**	Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics	87904 ($182.11)	AACC, ACLA, ASCP, CLMA	ASM, 87903 ($687.79) + 87904 ($182.11)
THERAPEUTIC DRUG ASSAY				
801XX	Sirolimus	80197 ($19.17)	ASCP, ASM, CAP, CLMA, Abbott, Roche	AACC, ACLA 80158 ($25.23)

*Current Medicare national fee cap, frozen through 2008. **Code on Medicare physician fee schedule. CPT codes copyright American Medical Assn.

focus on: Genetic Testing Services

Medicare Urged To Change Gene-Based Test Policies

A federal committee advising Health & Human Services Secretary Michael Leavitt wants the Medicare program to do more to encourage wider clinical use and beneficiary access to health-related genetic tests and services. The panel is calling for policy changes to make Medicare coverage decisions more uniform nationwide, expand preventive testing for beneficiaries, and bring reimbursement in line with actual testing and service costs.

The changes are part of a series of coverage and reimbursement recommendations that the Secretary's Advisory Committee on Genetics, Health & Society (SACGHS) finalized during its meeting last month (*NIR, 26, 18/Jul 11 '05, p. 1*). The final report and recommendations will go to Leavitt in the fall.

Background

Genetic testing technologies are well established in paternity, forensic, and other DNA fingerprinting fields, and are common in blood banking, for infectious diseases such as HIV and hepatitis C, and for inherited disease such as cystic fibrosis. Gene-based testing also is increasingly being used to identify an individual's predisposition to a host of other diseases such as breast cancer. As advances in genetics and genomics demonstrate their potential to improve patient care, the pressure is on to formulate coverage and payment policies to promote adoption of more gene-based testing by government and private payers.

Final SACGHS Recommendations: Genetic Test Coverage, Payments

- ❑ Task a public-private group to craft guiding principles for coverage decisions.
- ❑ Assess existing evidence on genetic test validity, utility; fund studies to fill research gaps.
- ❑ Create Medicare benefit for more preventive services, including predictive and pre-dispositional genetic tests, that meet evidence standards.
- ❑ Consider "family history" when deciding whether a genetic test is reasonable and necessary and thus covered under Medicare.
- ❑ Establish a threshold to trigger a Medicare national coverage review when there is a set number of local coverage policies for a genetic test or service.
- ❑ Get CMS to use its inherent reasonableness authority to make Medicare genetic test payment rates consistent with actual costs and reduce payment variations.
- ❑ Allow non-physician health providers who are qualified to provide genetic counseling and who now bill "incident to" a physician's service to utilize the full range of CPT office visit codes available for genetic counseling. Also, permit them to qualify for a National Provider Identifier.
- ❑ Provide private payers and state Medicaid programs with necessary information to determine whether to cover a genetic test or service.
- ❑ Support training, continued education of health providers in genetics & genomics.

Gene-based testing empowers physicians and laboratory scientists to peer into an infectious organism or inherited disposition to disease at the molecular level, then apply that "inside information" to an individual patient for prevention and early detection of disease, and for diagnosis and treatment, including the proper medications. Advocates say this "personalized" medicine results in safer, more effective patient care and saves money for healthcare systems by reducing unnecessary or risky testing and treatments.

In its report to the HHS Secretary, SACGHS emphasizes that coverage of a particular

health-related genetic test or service should be supported by adequate evidence of its clinical validity and utility. Also, reimbursement for covered tests should be set at levels "that do not undermine this coverage or reduce appropriate patient access." While the committee's recommendations address other federal programs, private health plans, researchers, and certifying bodies for health professionals, the changes sought in Medicare policy are especially significant because private payers typically follow Medicare's lead and Medicare sets the maximum that state Medicaid programs are allowed to pay for covered testing.

SACGHS Roster

The HHS Secretary's Advisory Committee on Genetics, Health & Society has 13 members appointed to staggered terms, plus 19 ex officio* members.

CHAIR
Reed V. Tuckson, MD (2007)
Senior VP, UnitedHealth Group
Minnetonka, MN

MEMBERS (appointed)
Sylvia Mann Au, MS, CGC (*new*)
Hawai'i State Genetics Coordinator
Honolulu, HI

Cynthia E. Berry, JD (2007)
Partner, Powell Goldstein Frazer & Murphy
Washington, DC

Cira Chen (new)
Comprehensive Cancer Center
University of California, San Francisco

James P. Evans, MD, PhD (*new*)
Dept. of Medicine, University of North Carolina
Chapel Hill, NC

Kevin T. Fitzgerald, SJ, PhD (*new*)
Chair, Catholic Health Care Ethics
Georgetown University Medical Center
Washington, DC

C. Christopher Hook, MD (2007)
Director, Ethics Education
Mayo Medical School
Rochester, MN

Debra G.B. Leonard, MD, PhD (2006)
New York Presbyterian Hospital, Cornell Campus
New York, NY

Julio Licinio, MD (*new*)
Neuropsychiatric Institute, David Geffen School of Medicine
University of California at Los Angeles

Agnes Masny, RN, MPH, MSN (2006)
Family Risk Assessment Program
Fox Chase Cancer Center
Philadelphia, PA

Joseph Telfair, Dr.PH, MPH, MSW (2008)
Dept. of Maternal and Child Health
University of Alabama, Birmingham

Huntington F. Willard, PhD (2007)
Vice Chancellor, Genome Sciences
Duke University
Durham, NC

Emily S. Winn-Deen, PhD (2006)
VP, Strategic Planning & Development
Cepheid
Sunnyvale, CA

*Representing CMS, FDA, Depts. of Commerce, Defense, Labor, Energy and Veterans Affairs, the Federal Trade Commission, the HHS Health Resources & Services Administration, National Institutes of Health, and others

'Thinking Outside The Box'

In calling for expanded Medicare coverage of more genetic tests and services used for preventive purposes, such as predictive and pre-dispositional tests, SACGHS made a special effort to "think outside the box," said Cynthia Berry, JD, who chaired the committee's task force on coverage and reimbursement. Berry is a partner in the law firm of Powell Goldstein Frazer & Murphy in Washington, DC.

While urging the HHS Secretary to lobby Congress to add a Medicare benefit category for such preventive services, the panel recognized that this could take a long time, so in the interim, it wants the Secretary to exercise his authority over Medicare regulations and interpretive guidelines in creative ways. Specifically, the Secretary should direct the Centers for Medicare & Medicaid Services to clarify that, in certain circumstances and where scientific evidence warrants, "family history" should be considered as "personal history" in determining coverage for a particular test or service.

Unless directed otherwise, Medicare officials have traditionally interpreted Medicare law to exclude "screening services," Berry noted in an interview with *NIR*, even though this term is not in the law. The law defines the basic rule of coverage in terms of what the program will not pay for: namely, "services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member…" SACGHS believes that, given what is known about genetic inheritance and predispositions, HHS has the regula-

Ban On Genetic Discrimination Still A Top Action Priority

SACGHS continues to urge the HHS Secretary to lobby Congress to enact comprehensive federal legislation to prohibit health insurers and employers from discriminating against individuals with a genetic predisposition to disease. This is needed, the panel says, to overcome public fears that genetic information could be used against them.

SACGHS reiterated its support for such legislation at its June meeting, following a briefing on a House bipartisan bill (H.R. 1227), introduced by Rep. Judy Biggert (R-IL) and similar to a Senate-passed version—S. 306, sponsored by Maine Republican Olympia Snowe (*NIR, 26, 9/Feb 21 '05, p. 1*).

Under both bills, health insurers could not exclude individuals with a genetic predisposition to disease from coverage, charge them higher rates, or require them to undergo genetic testing. Employers could not use genetic information to hire or fire workers. Medigap policies could not discriminate on the basis of genetic information. H.R. 1227 also tailors penalties for violations to the size of the company.

In 2003, similar anti-discrimination legislation cleared the Senate, but died in the House. The House vehicle, sponsored by Rep. Louise Slaughter (D-NY), attracted broad bipartisan support (242 co-sponsors). This time around, backers hope a GOP-sponsored bill will have better traction. Biggert's bill has been referred to three House committees (in contrast, Snowe's bill had to clear only one committee). The Bush Administration has said it supports a legislative ban on genetic discrimination by insurers and employers.

An analysis prepared for SACGHS concluded that current federal law (such as HIPAA, ADA, and ERISA), varying state laws, and differing court decisions don't adequately address issues raised by the use of genetic information, so a comprehensive federal approach is needed. This will help ensure privacy while encouraging expanded use of genetic testing services in clinical practice, the analysis said.

tory flexibility to specify what genetic testing will be covered in certain circumstances, for example, by interpreting "family history" as "personal history," thus taking it outside the "screening box" and into the "diagnostics box," Berry said.

In recent years, Congress has mandated Medicare coverage of more and more screening services, and for some (like diabetes and glaucoma screening), it has specified "family history" as a factor that warrants coverage.

Automatic Trigger For National Policy Review

Currently, Medicare makes coverage decisions for genetic tests and services via a mix of national and local contractor policies. While this is reasonable, SACGHS says, it has some drawbacks. One remedy, the panel notes, is to encourage CMS to move ahead on implementing Section 731 of the 2003 Medicare Modernization Act. This requires CMS to develop a plan to evaluate new local coverage decisions with an eye toward ascertaining which should be adopted nationally and to what extent Medicare can achieve greater consistency in its coverage policies.

As a further prod, SACGHS wants CMS to set a threshold that would automatically trigger a national coverage review for any test or service that is approved for coverage by a defined number of local contractors.

Improving Medicare Payment

Laboratory and pathology interests have long argued that Medicare payment for genetic testing services is lower than the actual cost of providing them. Currently, genetic test CPT codes are stuck at 2003 levels in accord with the five-year freeze (2004 through 2008) that Congress has imposed on the Part B lab fee schedule.

Still, SACGHS says, until the fee schedule can be reconsidered in a comprehensive way, the Secretary should direct CMS to "expeditiously" use its inherent reason-

ableness authority to adjust fees for genetic test CPT codes. Under this authority, Medicare can adjust lab and other Part B pay rates up or down by no more than 15%. The presumption is that genetic test rates would go up to better align with actual costs.

The panel also advocates payment policy changes to support genetic test interpretation and counseling in order to help integrate genetic testing services into medical practice. Among the recommendations:

- ❑ Identify an appropriate entity to determine which health professions are qualified to provide genetic counseling services, and among those qualified, which professions should be able to practice without physician supervision and bill payers directly.
- ❑ HHS should evaluate whether existing CPT evaluation & management codes and associated relative values are adequate for genetic counseling services.
- ❑ CMS should allow non-physician health providers who are qualified to provide genetic counseling services and who currently bill "incident to" a physician to utilize the full range of E&M codes available for genetic counseling services.

Commenting on the committee's work, Berry told *NIR* that SACGHS has two important roles. It gives the Secretary independent guidance, and through the involvement of its ex officio members, it is an information-sharing forum for the many federal agencies already dealing with diverse issues in genetic testing services. A lot of officials are addressing the issues, Berry said, and SACGHS is a regular forum that can help them coordinate their efforts. The next meeting is scheduled for later this year, on October 15-20.

Five Commonly Ordered Gene-Based Tests

Name	*Avg. Price**
BracAnalysis	$3,500.00
Cystic fibrosis genetic analysis	168.73
Factor V Leiden	71.02
Hepatitis C virus genotyping	250.00
Human papillomavirus (HPV-high risk)	65.53

*Average price charged by reference labs to perform test (after discounts).
Source: Washington G-2 Reports' *Second National Esoteric Testing Survey*

Direct-To-Consumer Marketing

At their June meeting, SACGHS members were briefed on the Food & Drug Administration's role in oversight of direct-to-consumer (DTC) marketing of genetic testing services. This refers to advertising and direct access to testing without the involvement of a health professional.

In the past, the committee has expressed concerns about some of the advertising claims reported, for example, that an individual's nutritional needs can be determined by a genetic test and that genetic tests can predict a child's propensity for addictive behaviors. The panel has also been concerned that consumers could forgo necessary treatments or undergo unnecessary or risky treatments in response to invalid test results. Harm could also result if the individual acted on misinterpreted results even when the test is valid.

The FDA's role in oversight of DTC is uncertain at this point, and the agency has not clearly defined Internet promotion as labeling or advertising, Deborah Wolf, JD, told the committee. Wolf is with the Office of Compliance at FDA's Center for Devices & Radiological Health.

The FDA is, however, tracking issues raised by claims made for drug metabolism and reactions; nutritional counseling, vitamins, and obesity; and detecting susceptibility to cardiac disease, cancers, osteoporosis, autoimmune disease, fatigue syndromes, and infectious diseases. It also is monitoring information on selected laboratory Websites.

The FDA has cleared about 12 genetic test kits for commercial use, Wolf said, including kits for newborn screening, metabolic enzyme measurements, and cystic fibrosis. But most genetic tests are developed in-house at labs, and FDA regulates only the active ingredients, known as analyte-specific reagents.

Senate Panel Rescues Title VII Allied Health Training Funds

The final Senate version is expected to retain the restored money. Differences would have to be ironed out by a House-Senate conference

As it has before in recent years, the Senate Appropriations Committee has voted to restore Title VII health professions training support in fiscal 2006 to its current level of close to $300 million. The move came in recent final action on the HHS-Labor-Education spending bill. The House-passed version, like the President's budget request, eliminated virtually all funding and reduced support for scholarships for disadvantaged students and the Centers for Excellence program (*NIR, 26, 18/Jul 11 '05, p. 3*).

According to an analysis by Dionne Braddix at the American Society for Clinical Pathology (Washington, DC), the training account for allied health and other disciplines, which includes a small portion for the training of medical technologists and medical lab technicians, was restored to $11.77 million. Current funding levels were also restored for the Centers for Excellence Program ($33.6 million) and scholarships for disadvantaged students ($47.1 million).

Medical Errors Bill Moves In the House

The Senate HELP Committee passed its patient safety bill (S. 544) in March. E&C health subcommittee chair Nathan Deal (R-GA) has said he'd like to work out differences before his measure goes to the full E&C Committee

Bipartisan legislation to encourage voluntary, confidential reporting of medical errors, including laboratory mistakes, and the use of this information to improve patient safety was approved July 14 by the House Energy & Commerce Subcommittee on Health (*related story, NIR, 26, 17/Jun 20 '05, p. 6*). The bill (H.R. 3205) is similar to one the House approved in the last Congress, the panel says.

H.R. 3205 would provide peer review protection of healthcare errors that providers report to patient safety organizations (PSOs), which would analyze the data and share the findings. The protection would apply to certain categories of documents and communications, described as patient safety work product, that are developed in connection with the PSOs. The work product would be privileged. "It is intended that providers, with the assistance of the PSOs, will determine the causes of these errors, identify what changes need to be made in the healthcare delivery system in order to prevent these errors, and then implement the changes," said the health panel.

Pennsylvania Leaves Door Ajar On Medicaid Lab Co-Pay

Pennsylvania state legislators dropped a proposed co-pay of up to $3 for Medicaid laboratory services from the final budget that Gov. Edward Rendell (D) signed into law on July 7. Clinical laboratory groups had lobbied hard to scuttle the proposal (*NIR, 26, 13/Apr 25 '05, p. 3*). But the issue isn't dead yet. The legislators tossed it to the state Department of Welfare, giving the agency authority to change Medicaid rates, benefits, and co-pay requirements until December 31 of this year. Lab groups are especially concerned that the Department could impose changes without going through a formal comment process.

Meantime, with rising healthcare costs a top priority for states, momentum is growing to require more Medicaid co-pays. This was one of the major changes backed by the National Governors Association at its annual meeting on July 18. The NGA also wants to tighten rules to prevent seniors from giving away their assets to qualify for Medicaid-funded long-term care.

House Health Leaders Prod CMS On Physician Fee Fix

Bipartisan bills recently introduced in the House and the Senate would mandate a minimum 2.7% increase in Medicare physician fees in 2006 (NIR, 26, 16/ Jun 6 '05, P. 3)

Key House lawmakers want Medicare officials to take administrative steps to avert a scheduled cut of 4-5% in next year's update to physician fees. The steps include removing prescription drug expenditures from the sustainable growth rate (SGR) formula and accounting for the costs of new Medicare benefits. Fixing the SGR "would be prohibitively expensive given current interpretations," said House Ways & Means chairman Bill Thomas (R-CA) and health subcommittee head Nancy Johnson (R-CT), in a July 12 letter to Mark McClellan, administrator of the Centers for Medicare & Medicaid Services.

Congress has stepped in before to avert physician fee cuts and approved a slight increase—1.5% for 2004 and 2005. Nonetheless, physician pay rates are projected to " decline more than 31% from 2005 to 2010, while the cost of providing services would increase by 19%," the letter said. "This is simply unacceptable."

Thomas and Johnson also said Medicare should link physician payments to performance (note: CMS this year began a P4P pilot with 10 large physician groups, *NIR, 26, 8/Feb 7 '05, p. 8*). At press time, a House legislative draft reportedly would repeal the SGR, raise fees in 2006, but starting in 2007, reserve the full update for physician groups who report on performance criteria (those who don't would get less). In the Senate, Finance Committee leaders have unveiled a Medicare value-purchasing bill that would apply to physicians and other providers (*NIR, 26, 18/Jul 11 '05, pp. 1-2*).

washington WATCH

Crawford Wins FDA Nod, But Doubts Persist

The Senate voted 78-16 to confirm Lester Crawford as FDA commissioner after several senators lifted their holds on his nomination when the FDA promised to issue rules by September 1 for an over-the-counter emergency contraception pill. The nomination was also mired in controversy over alleged travel irregularities involving a personal relationship with a female FDA staffer, but the charges were dismissed after an HHS OIG investigation.

Crawford failed to win support from Senate Finance leaders Charles Grassley (R-IA) and Max Baucus (D-MT). Grassley said Crawford wasn't the right person to make needed changes at FDA to protect the public interest. Ironically, perennial FDA critic Edward Kennedy (D-MA) voted for confirmation, but said he would closely monitor FDA's handling of drug safety and other issues (see also *NIR, 26, 9/Feb 21 '05, p. 8*).

Crawford has been acting FDA commissioner for the last year and previously was deputy commissioner.

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