I. Introduction

A. Clinical laboratory services are provided in a variety of settings, including hospitals, independent clinical laboratories and physician offices.

B. Clinical laboratory testing is covered under Medicare under § 1861(s)(3) of the Social Security Act. Physician pathology testing is considered, and paid for, as a physician service. See Medicare Claims Processing Manual (MCPM), Ch. 12 § 60.

C. The mapping of the human genome has given rise to new types of genetic testing and the prospect of “personalized medicine.” As a result, there has been increased attention on issues related to clinical laboratory testing.

D. The purpose of this presentation is to provide some background on significant regulatory and compliance issues facing clinical laboratories.

II. Significant Recent Changes

A. As discussed below, recent growth in molecular diagnostics testing has caused several new developments.

1. Palmetto, the former MAC for California, has developed special billing and coverage requirements for these tests under its “MolDx Program.”

2. CMS used the “gapfilling” process to establish payment levels for many of these tests, which were assigned new CPT codes in 2012.

B. In the 2014 Physician Fee Schedule Rule, CMS adopted a proposal that will allow it to revise the pricing for commonly performed clinical laboratory tests based on “technological changes” that have occurred since the laboratory fee schedule was developed in 1984.

C. The Clinical Laboratory Improvement Amendments were amended in 2012, to give CMS greater discretion in cases of accidental proficiency testing referrals by laboratories, thereby eliminating some of the hardships that had accompanied such cases previously.

D. The FDA continues to state that it expects to issue some type of guidance with regard to Laboratory Developed Testing (LDT), although so far it has not done so.

E. These developments and other recent changes are marked in this outline as “Recent
III. Basic Requirements for Laboratories

A. Coverage of Laboratory Testing

1. CLIA certification


b. Medicare will not pay for any laboratory services, unless the laboratory is certified under CLIA to perform the services. Soc. Sec. Act, § 1861(s)(17)(A).

c. CLIA establishes different regulatory requirements for laboratories depending on the complexity of the testing being performed. Id. at § 493.5.

d. The current complexity levels are:

i. Waived testing, which is subject to the lowest level of regulation.

ii. Provider performed microscopy testing, which is applicable to certain specific tests performed by physicians or other practitioners for their own patients.

iii. Moderate complexity testing.

iv. High complexity testing.

e. Virtually all laboratories performing testing must be certified in one of these levels.

f. CMS has granted some organizations, such as the College of American Pathology (CAP) and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) “deemed” status, and permits them to accredit laboratories. Two states, New York and Washington, are exempt from CLIA because their status programs are at least as stringent as CLIA. For more information on CLIA, go to www.cms.hhs/CLIA.

g. CLIA imposes standards in the following areas, based on the level of certification.

i. Proficiency testing (subpart H)

ii. Quality control (subpart K)
iii. Personnel requirements (subpart M)

iv. Inspection (subpart Q)

v. Enforcement procedures (subpart R)

h. The most significant enforcement issue, under CLIA, involves the improper referral of proficiency testing specimens.

i. Any laboratory that is found to have intentionally referred a PT sample to another laboratory for analysis, will have its certification revoked for at least one year. Id. at 493.801(b)(4).

ii. CMS had stepped up its enforcement in this area and acted aggressively when improper PT referral was discovered.

iii. **Recent Development:** In 2012, Congress passed the Taking Essential Steps for Testing (TEST) Act, which gave CMS greater discretion in cases where a laboratory referred a proficiency testing sample. As a result, revocation of a laboratory’s CLIA certificate is not always mandatory in cases where a laboratory accidentally refers a PT sample.

   (A) CMS has issued draft regulations to implement this provision. See 78 Fed. Reg. 58386 (Sept. 23, 2013). It also issued an earlier set of regulations on the same topic as part of a separate rulemaking effort. See 78 Fed. Reg. 9216 (Feb. 7, 2013).

2. Medical necessity

   a. As with all Medicare services, laboratory services must be medically necessary. Soc. Sec. Act, § 1862(a). CMS generally interprets this to mean that it does not pay for “screening services.” See 42 C.F.R. § 411.15(a)(1).

   b. Medical necessity is a complicated issue for laboratories, as they do not usually determine what tests are ordered. That decision is usually made by the physician.

   c. As discussed below, the Office of Inspector General (OIG) takes the position that it is the laboratory's responsibility to inform physicians concerning applicable Medicare requirements.

   d. To ensure that Medicare only pays for medically necessary testing, Medicare contractors (i.e., Medicare Administrative Contractors (MACs), carriers and fiscal intermediaries) often require laboratories to submit diagnosis codes, referred to as ICD-9 codes, for some laboratory testing.

   i. These requirements are implemented either through national policies or
through contractor initiated Local Coverage Decisions (LCDs). Under LCDs, contractors list the particular ICD-9 codes that they will acceptable for each test. If a laboratory submits a claim without an acceptable code, then the claim will be denied.

ii. The physician must supply the ICD-9 code to the laboratory; the laboratory cannot usually determine the code itself. Laboratories can translate supplied narrative diagnoses into ICD-9 codes, however.

iii. Where the physician provides a non-covered code, however, the laboratory may obtain, or may ask the physician to obtain, an ABN prior to performing the testing. Where it obtains a valid ABN, the laboratory may then bill the beneficiary if Medicare denies payment. As discussed below, CMS has issued a new ABN form and instructions.

iv. In the past, concern was raised because there were often differences between the ICD-9 codes that were accepted in different carrier jurisdictions. The laboratory industry argued that this led to inconsistent payment decisions. As a result, in the BBA, Congress mandated the negotiated rulemaking to establish national coverage policies for some laboratory tests. See Pub. L. No. 105-33, § 4552, 1997 U.S.C. A.A.N. (111 STAT.) 460. The final rule resulting from that negotiated rulemaking was published on November 23, 2001. See Section V, below.

3. Screening testing

a. As noted above, in most instances, Medicare does not pay for screening testing, because it is not considered "medically necessary."

b. However, there are certain specific types of screening services that Medicare does pay for.

i. As a result of changes made by BIPA, beginning in July 2001, Medicare paid for a screening Pap smear every two years, rather than every three. Soc. Sec. Act, § 1861(nn). Medicare will also pay for an annual Pap smear if the woman is considered at high risk of cervical or vaginal cancer.

ii. Medicare also pays for a fecal occult blood test annually for beneficiaries aged 50 and older. Soc. Sec. Act, § 1861(pp).

iii. Under the BBA, Medicare pays for Prostate Specific Antigen testing ("PSA") annual for Medicare beneficiaries over 50, beginning in the year 2000. Id. at § 1861(oo).

4. Other related laboratory services
a. Medicare also pays a specimen collection fee of $3.00 for the drawing or collection of specimens. Payment is only made to the person or entity that actually performs the drawing, however. See MCPM Ch. 16 § 60.1.

b. Travel fees

i. Medicare will pay for a travel allowance to cover the cost of having trained personnel travel to a nursing home or home bound patient to collect a specimen.

ii. Travel fees are not permitted, however, if the laboratory is simply picking up a specimen, rather than actually drawing a specimen.

iii. In August 1998 CMS issued a new policy establishing the payment rules for determining travel allowances. The methodology will vary depending on whether the trip is greater or shorter than 20 miles. MCPM, Ch. 16, § 60.2.

B. FDA Issues for Lab Testing

1. In general, Medicare does not pay for services that are experimental or investigational. 42 C.F.R. § 411.15(o).

a. As a result, Medicare will not usually pay for testing services performed using test kits that have not been cleared or approved by FDA. Medicare Benefit Policy Manual (MBPM) Chap. 14, § 80.

b. An exception is made for devices classified as “Category B” devices by FDA. These are unapproved devices where the underlying questions of safety and effectiveness have been resolved because, for example, other similar types of devices have already been cleared or approved. Id. § 20.

c. Medicare contractors make coverage determinations for Category B devices. Id. § 50.

2. Historically, however, FDA has not regulated “Laboratory Developed Tests” (LDT), also called “home brew” tests, which are tests developed in house by a single laboratory and not “commercialized.” As a result, these tests are eligible for Medicare payment. However, FDA has announced it is considering greater regulation of LDTs, as discussed below.

a. ASRs are reagents used by laboratories in the creation of LDTs.

b. The FDA determined that most such devices could be classified as Class I devices, and thus were exempt from FDA premarket approval.

c. Importantly, the FDA recognized in the ASR rule that “in-house developed tests [have] contributed to enhanced standards of medical care.” *Id.* at 62249.

d. Certain other types of ASRs, which required special or greater controls, were classified as Class II or III. Tests used to diagnose contagious diseases, such as HIV or TB, were classified as Class III and require premarket approval.

e. ASRs may only be sold to laboratories certified under CLIA to perform "high complexity" testing. Laboratories using such devices also must comply with various quality control requirements required by CLIA.

f. FDA requires laboratories using ASRs to put a special disclaimer on the test report. The disclaimer should state:

“This test was developed and its performance characteristics determined by [laboratory name]. It has not been cleared or approved by the U.S. Food and Drug Administration.”

*Id.* at 62246.

g. The FDA has recently issued new Guidance on ASRs that may limit the applicability of the ASR rule to some newly developed products. See *Guidance for Industry and FDA Staff: Commercially Distributed Analyte Specific Reagents (“ASRs”): Frequently Asked Questions (2007)*, available at www.fda.gov/CDRH/OIVD/Guidance/1590.pdf.

4. RUO/IUO testing

a. At various times, the FDA has also expressed concern about the use of Research Use Only (RUO) and Investigational Use Only (IUO) test kits; i.e., those test kits that were being labeled for use for investigational or research purposes, and thus were not being formally approved by the FDA.

b. Several years ago, the FDA issued a *draft* Compliance Policy Guide (CPG) that would have applied to the commercialization of in vitro diagnostic products. The final version of the CPG was never issued.

c. **Recent Development:** In 2013, FDA issued a Final Guidance entitled “Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only,” which imposed greater restrictions on manufacturers’ distribution RUO and IUO devices. FDA said it would use a “totality of the circumstances approach” in determining whether a
manufacturer was inappropriately promoting a product for clinical use, despite the RUO/IUO labeling.

5. Other issues related to FDA regulation of new tests are discussed in Section IV, below.

C. Rules Applicable to Test Ordering

1. Physician ordering rule

a. Medicare requires that the test be ordered by the physician or other authorized person who is involved in treating the patient. 42 C.F.R. § 410.32. CMS has recognized, however, that the patient may have more than one treating physician. 61 Fed. Reg. 59497-98 (Nov. 22, 1996).

b. Non-physician practitioners (such as clinical nurse specialists, clinical psychologist, clinical social workers, nurse midwives, nurse practitioners, and physician assistants) who provide services that would be covered as physician services, if furnished by a physician, may be considered physicians under the treating physician rule. They must be acting within their authority under state law and within the scope of their Medicare statutory benefit. 42 C.F.R. § 410.32(c).

c. CMS has clarified that a pathologist could order certain additional tests on a pathology specimen that he or she received, without violating the treating physician rule. MBPM, Chap. 15, § 80.6.5. The following conditions must be met, however.

i. The services must be medically necessary so that a complete and accurate diagnosis can be reported to the treating physician or practitioner.

ii. The results are communicated to, and used by, the treating physician or practitioner in the treatment of the beneficiary.

iii. The pathologist documents in his report why additional testing was done.

2. Physician signature requirements

a. The question of whether or not a physician signature is required on a laboratory requisition is one that has been the subject of frequent discussion over the past few years.

b. The issue was explicitly discussed during the Laboratory Negotiated Rulemaking. At that point, it was decided that while a signature was one way of showing a valid order, it was not the only way. See 66 Fed. Reg. at 58801-02; Prog. Memo, AB-02-030 (Mar. 5, 2002).
c. Under CLIA, the physician's *name* must be on the order or requisition, however. Some *Medicaid* programs do, however, require the physician to sign the test order.

d. CERT contractors and CMS have recently been rigorous in enforcing the treating physician rule. Where the requisition is not signed, CMS requires there must be documentation in the medical record that the treating physician intended to order the service. This documentation must be authenticated by a handwritten or electronic signature. Medicare Program Integrity Manual, Chap. 3, § 3.4.1.1.

e. When CMS initially updated the Internet Medicare Benefit Policy Manual, it left out prior statements that a laboratory order did not have to be signed; however, subsequently, CMS corrected this omission. *See* “Physician Signature Requirements for Diagnostic Tests,” Trans. 94, Chge. Req. 6100 (Aug. 29, 2008).

f. In the 2010, PFS rule, CMS announced that it was “clarifying” its policy with regard to physician signature requirements. It stated that a signature was not required on a *requisitions* for tests paid on the basis of the Clinical Laboratory Fee Schedule (CLFS), however, it had to be evident that the physician had ordered the services.

   i. CMS stated it only applied to “requisitions” as opposed to “orders.”

   ii. A written order for other services, such as the Technical Component of a pathology service would still require a signature.

   iii. After negative comments, CMS took no final action, but said it would revisit the issue in the future.

g. In the 2011 PFS Proposed Rule, CMS announced it was changing its requirement and would require a physician’s signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS.

   i. CMS said it would be less confusing and would eliminate uncertainty about what was required.

   ii. CMS stated that it would not increase the burden on physicians because it believed most physicians already annotated the medical record.

   iii. CMS said the requisition was the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient.

   iv. The reaction was universally negative, from the major laboratory organizations, the College of American Pathologists, the AMA, and the AHA, as well as groups representing nursing homes.
v. Commenters expressed numerous concerns:

(A) The major concern was that physicians did not usually sign requisitions, and that laboratories had little power to force them to do so, as the lab, rather than the physician, was the one being paid.

(B) What would happen if physicians failed to sign the requisition; could the laboratory go back after the fact and obtain the signature?

(C) How would this apply to nursing homes, where the physician often was not present to sign the requisition?

(D) What was the difference between the requisition and the order? How would this apply to pathology tests, which were not paid on the CLFS?

vi. CMS initially adopted the new policy in the 2011 Final Physician Fee Schedule Rule requiring a physician signature on an order or requisition for clinical laboratory services, although it subsequently agreed to delay the implementation of the requirement.

vii. After further discussion, however, in the 2012 Physician Fee Schedule Rule, CMS withdrew the requirement that the requisition had to be signed, although it continued to require that there be a signed order for the test in the medical records. See 76 Fed. Reg. at 73301 et seq. (Nov. 28, 2011).

3. In addition, CLIA also imposes certain other information requirements related to test-ordering. See 42 CFR § 493.1105.

4. Oral requests

a. Oral requests are permitted for testing. It is not unusual, for example, for a laboratory to receive a request from a physician to add testing to a requisition that the laboratory had already received.

b. CLIA requires that the laboratory request written authorization for testing within 30 days of the test; however, CMS has recognized that the laboratory may be unable to receive the acknowledgment back. 42 C.F.R. § 493.1105. See also, 58 Fed. Reg. at 5218 (Jan. 19, 1993).

c. A recent revision to the treating physician rule states that if an order is communicated by phone, both the treating physician and the testing facility must document the call in their records. MBPM, CMS Pub. 100-02, Ch. 15 § 80.6.1.
D. **New Developments: Test Reporting Requirements**

1. CLIA also requires that test reports only be provided to an authorized person. 42 C.F.R. §493.1291 (f).

2. For purposes of CLIA, an “authorized person” is anyone authorized under state law to receive test results.

3. Because many states required that only physicians and health care providers were permitted to receive test reports, this provision was interpreted to prevent patients from being able to obtain their laboratory results, even though HIPAA usually permits a patient to obtain his or her own medical records.

   
a. It amends the CLIA regulations to require a laboratory to provide the patient, his or her patient representative, or other designated person with copies of completed test reports.
   
b. The laboratory, however, must authenticate that the person is authorized to obtain the test results.
   
c. The Rule removes the previous HIPAA exemption that existed, which prevented patients and their representatives from being able to access their own information.
   
d. In addition, the Rule explicitly overrules inconsistent state laws that otherwise would prevent the patient from obtaining his or her information.
   
e. Laboratories must comply with these requirements by October 6, 2014.

E. **Medicare Payment Rules**

1. Who can bill and be paid for laboratory testing?
   
a. For inpatients, clinical laboratory services are included in the DRG payment made to the hospital. Independent clinical laboratories cannot bill separately for services covered by the DRG payment; those services must be billed to the hospital “under arrangements.” Soc. Sec. Act, § 1862(a)(14).
   
b. Until recently, reimbursement for clinical laboratory services furnished to outpatients was not made under the outpatient PPS system. Outpatient laboratory services were paid on the basis of the clinical laboratory fee schedule. However, laboratory services to outpatients must be billed by the hospital. If performed by an outside laboratory, they must be billed to the hospital “under arrangements.” See 63 Fed. Reg. at 47552, 47560 (Sept. 8, 1998).
i. **New Development.** Under the 2014 Final Outpatient Hospital Rule, however, CMS decided to bundle the clinical laboratory services into the hospital’s APC payment when they are integral, ancillary, supportive, dependent or adjunctive to a primary hospital service. See 78 Fed. Reg. at 74939 (Dec. 10, 2013).

ii. This will usually apply when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who orders the primary service.

iii. CMS says it will except from this requirement molecular pathology tests, which it believes have a different pattern of use.

c. For non-hospital patients, the services are paid on the basis of the clinical laboratory fee schedule.

i. Usually, the laboratory performing the testing must bill and be paid for testing.

ii. However, an independent laboratory may bill for testing that it refers to another laboratory, so long as the **referring laboratory** performs on site at least 70% of the testing for which it receives requests annually. See Soc. Sec. Act § 1833(h)(5)(A).

d. For SNF patients, laboratories must bill the SNF for services furnished to patients in a Part A stay; for patients covered by a Part B stay, the laboratory has the option of either billing the SNF or billing Part B directly. See MCPM, Ch. 16, § 40.4.

e. Similarly, for dialysis patients, laboratories must bill the dialysis facility for tests covered by the bundled rate, but can bill Part B for other testing services. On August 12, 2010, CMS issued new payment rules for dialysis services, which significantly expanded the list of tests that must be billed back to the dialysis facility. See 75 Fed. Reg. 49030 (Aug. 12, 2010.)

2. The Medicare fee schedule

a. The clinical laboratory fee schedule applies to all clinical laboratory testing payable under Part B of Medicare for non-hospital patients, regardless of where it is performed. Fee schedules are set on the basis of carrier jurisdiction. Soc. Sec. Act, § 1833(h)(1).

b. By law, the laboratory fee schedule is supposed to be increased annually to reflect changes in CPI. However, Congress has routinely reduced or frozen this update to capture budget savings. The full CPI update has only been applied twice in the last 20 years. In 2008, in MIPPA, Congress reduced the CPI update by .5% for the next five years. Pub. L. No., 110-275, § 145(b). As a result, in January 2009, laboratories received a 4.5 update.
i. Because of the falling CPI, and the .5% reduction, the clinical laboratory fee schedule received a 1.9% cut in 2010.

ii. Under health care reform, the following changes were made to laboratory reimbursements:

(A) The .5% reduction in the CPI imposed by MIPPA was eliminated.

(B) Instead, a new productivity adjustment, which was applicable to other payors, was imposed on the CPI.

(C) An additional reduction of 1.75% is also applied, for 2011 through 2015.

(D) The productivity adjustment cannot reduce the CPI below zero, but the 1.75% reduction may result in a negative adjustment. PPACA, § 3401(l).

iii. New Development: In addition, in the Middle Class Tax Relief and Job Creation Act of 2012, Congress mandated that CMS rebase the fee schedule on a one-time basis to effect an additional 2 percent across-the-board reduction in the fee schedule.

c. In addition, there is a national cap on the amount that Medicare will pay for laboratory services. Currently, that cap is set at 74% of the median of all the fee schedules for each test. Soc. Sec. Act, § 1833(h)(4)(B).

d. Laboratory services may be billed only on an assignment basis; i.e., directly to the Medicare program. There is no copay or deductible for laboratory services under Medicare, although a 20% laboratory copayment has been periodically proposed, as a budget savings option.

e. Competitive Bidding Demonstration

i. In MMA, Congress required CMS to enact a demonstration project utilizing competitive bidding for lab services. Pub. L. 108-173. § 302(e). The proposal followed similar efforts for DME, and was to have two different projects in different states.

ii. CMS announced the first lab demo for San Diego, to begin in April 2008.

(A) Court found CMS should have proceeded through rulemaking.

(B) Court also found irreparable harm to smaller labs if the demonstration was allowed to proceed.

iv. After the enactment of MIPPA (discussed below), the government moved to have the case dismissed as moot. However, the industry opposed the motion on the grounds that the government should be required to return or destroy the information. After discussions, the case was settled and the underlying action dismissed.


f. **New Development.** In the 2013 Final Physician Fee Schedule Rule, CMS announced a new plan to adjust pricing on the Clinical Laboratory Fee Schedule to reflect technological changes that have occurred since the CLFS was first developed. *See* 78 Fed. Reg. 74230, 74441 (Dec. 10, 2013).

i. CMS noted that the CLFS is one of the few payment methods used by Medicare that is not routinely updated to reflect new technology.

ii. Under § 1833(h)(2)(A)(i), the Secretary is permitted to make adjustments that are justified by technological changes, although CMS had never used that authority previously.

iii. As a result, each year in the Proposed PFS Rule, CMS will identify codes that it believes should be adjusted, beginning with the 2015 Proposed Rule.

(A) It will identify the test code, discuss how it has been impacted by technological change, and propose an adjustment to the payment amount to reflect the change.

(B) Adjustments could be made up or down, but CMS states it expects the adjustments will usually be down.

(C) Adjustments would be finalized in the Final PFS Rule, and would be effective beginning in 2015.

(D) Initially CMS proposed that it would only look at tests when they had been on the CLFS for 5 years, and would begin with the oldest codes first. However in the Final Rule, CMS decided against the 5-year limitation and decided it would look at other factors such as spending growth, high dollar payment and volume, in prioritizing which codes to look at first.
(E) CMS initially estimated that it would take about 5 years to review all of the 1250 codes on the CLFS.

3. New Clinical Diagnostic Laboratory Test Pricing

a. There are two ways to determine payment levels for clinical laboratory diagnostic tests for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (“new tests”). 72 Fed. Reg. 66222, 66275 (Nov. 27, 2007).

i. “Cross-walking” is used if a new test is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. If cross-walking is applied, CMS assigns to the new test code the existing local fee schedule amounts and national limitation amount (NLA) of the existing test code or codes. If CMS crosswalks to multiple existing test codes, CMS determines the local fee schedule amounts and NLA based on a blend of payment amounts for the existing test codes.

ii. “Gapfilling” is used when no comparable existing test is available. Carriers are instructed to determine a carrier-specific amount for use in the first year that the new code is effective. After the first year, the carrier-specific amounts are used to calculate the NLA for subsequent years. The sources of information that carriers examine in determining these amounts include:

(A) Charges for the test and routine discounts to charges;

(B) Resources required to perform the test;

(C) Payment amounts determined by other payers; and

(D) Charges, payment amounts, and resources required for other tests that may be comparable (although not similar enough to justify cross-walking) or otherwise relevant.

b. Price-setting process

i. Each summer, CMS holds a public meeting, announced in the Federal Register, to determine pricing for new tests that will be assigned CPT codes in the CPT Manual to be released later that year.

ii. Industry representatives provide input regarding:

(A) Whether a test should be gap filled or cross-walked; and

(B) For codes that are cross-walked, the codes to which they should be assigned.
iii. CMS reviews the information and announces its decisions in November, to be effective January 1.

iv. In the past, there has been a strong preference, both in the industry and CMS, for “cross-walking” new codes because gap-filling was often viewed as too unpredictable and lacking sufficient criteria.

c. Reconsideration process

i. CMS adopted a reconsideration process to permit stakeholders to appeal the basis of payment (i.e., cross-walking or gap-filling) and payment amount for any new test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008. 42 C.F.R. § 414.509.

ii. Commenters can submit written comments within 60 days of CMS’ announcement of new pricing. They would also have the opportunity to present their comments orally at the next clinical laboratory public meeting and hear other comments during the meeting.

iii. In addition to those who submit written comments, commenters may speak about reconsideration requests on the laboratory public meeting agenda.

iv. CMS will accept written comments on reconsideration requests addressed at the public meeting.

v. After considering the received comments, CMS will post its decision on the website as to whether it elected to reconsider the determination of the basis for payment or payment amount.

vi. If CMS changed its prior determination of the basis for payment or payment amount, the new determinations would be effective the following January 1.

vii. CMS proposed that the jurisdiction for reconsideration would rest solely with the Secretary. It would be in the Secretary’s discretion to determine whether or not to reconsider a determination. A refusal to reconsider an initial determination would not be subject to administrative or judicial review.

d. Gapfilling Interim Determinations

i. CMS will post interim determinations of carrier-specific amounts on the CMS website in April and for 60 days accept written comments that will be shared with carriers and MACs. 72 Fed. Reg. at 66277; 42 C.F.R. § 414.509(b)(2).
ii. In September, CMS will post final carrier-specific amounts on its website. At that point, interested parties may request reconsideration of the final carrier-specific amounts and the National Limitation Amounts (NLA) within 30 days of posting the amounts to the website.

iii. Based on the comments, CMS will determine whether it would reconsider the carrier-specific amounts and NLA.

iv. If CMS elects to reconsider the carrier-specific amounts and the NLA, CMS will process the request for reconsideration between the end of the 30-day comment period and the deadline for dissemination of the information to the carriers or MACs through CMS instructions so that the payment amounts are finalized by January 1.

v. If CMS elects not to reconsider the amounts, the amounts and NLA are posted on the CMS website on or before January 1.

vi. This determination would be final.

vii. CMS recently used the gap-filling process to establish the rates for molecular diagnostic tests, which recently received new CPT codes. That process is discussed below in Section IV.D.

4. Physician pathology testing

a. Certain services are paid for as physician services, rather than clinical laboratory services. These pathology services are paid under the physician fee schedule, not the clinical laboratory fee schedule. See MCPM, Pub. 100-04, Ch. 12 § 60.

b. Services included as physician pathology services are surgical pathology services; certain cytopathology, hematology and blood banking services; clinical consultation services; and specified clinical laboratory interpretation services.

c. Most pathology services include both a technical component (TC) and a professional component (PC).

d. The “TC Grandfather” provision

i. Until 1999, the rule was that an independent lab could bill for both the TC and PC, for a service furnished to hospital inpatients or outpatients. If the hospital provided the TC, however, it could not bill for it because then the service was considered part of the DRG or outpatient payment, whichever was appropriate.
ii. In 1999, CMS announced a change in this policy. In a policy that was to have been effective January 2001, independent laboratories were to bill hospitals for the TC of pathology services furnished to inpatients and outpatients, because, according to CMS, it was already paying the hospital for the service under the DRG and outpatient PPS payment.

iii. BIPA instituted a special “grandfather” provision, however, that permitted some of these arrangements to continue. According to § 542 of BIPA, if an independent laboratory furnishes the TC of a pathology service to an inpatient or outpatient of a “covered hospital,” that service is paid for as a physician service, and not considered part of the DRG or outpatient PPS payment.

iv. A covered hospital is one that had an arrangement with an independent laboratory in effect as of July 22, 1999, under which the laboratory billed for the TC. July 22, 1999 was the date CMS first proposed the change in TC billing for inpatients. MCPM, Ch. 16, § 80.2.1.

v. CMS permitted laboratories and hospitals to file an attestation to the carriers that the hospital qualifies as a “covered hospital.” Prog. Memo. B-01-50 (Aug. 8, 2001).

vi. The grandfather provision been repeatedly extended by Congress. Section 3104 of PPACA extended it until the end of 2010. It was extended again until December 31, 2011 by H.R. 4994, the Medicare and Medicaid Extenders Act of 2010, which was signed on December 15, 2010.

vii. **New Development.** In the Middle Class Tax Relief and Job Creation Act of 2012, however, Congress eliminated the grandfather provision for all services furnished after June 30, 2012. Therefore, since that time, laboratories have been required to bill hospitals for the TC of services furnished to hospital patients.

e. **New Development.** In the 2014 Proposed Fee Schedule Rule, CMS proposed a significant change in how it would pay for certain services, which would have had far reaching ramifications for pathology services. See 78 Fed. Reg. 43282, 43296 (July 19, 2013).

i. Under the Proposed Rule, CMS expressed concern about situations where the payment for a service furnished in a physician’s office exceeded the payment for the same service in a hospital setting.

ii. CMS stated that it believed these differences were due to inaccuracies in the date used to establish the Practice Expense component of the PFS.
iii. As a result, CMS proposed to limit the payment under the PFS so that the total payment amount would not exceed the amount that Medicare would pay for the same code in the facility setting. This would have had a significant impact on pathology services, because they can are routinely provided in both the hospital and the physician setting.

iv. After strong negative comments from most parties, CMS decided not to adopt this proposal when it issued the final 2014 PFS Rule. However, it noted it would continue to study the issue and would propose a revised proposal at a later time. See 78 Fed. Reg. at 74248 (Dec. 10, 2013).

F. Laboratory ABN

1. The ABN is used to give notice to a Medicare beneficiary when the provider believes Medicare may deny the services as not medically necessary.

2. In most instances, the laboratory will rely on the physician, who sees the patient, to furnish the ABN, although physicians are not required to assist the laboratories in getting the patient to fill out an ABN.

3. The previous ABN (ABN-L) allowed laboratories to customize the form, and list tests that would be denied under specific reasons for denial.

4. New ABN Form

a. On March 3, 2008, CMS implemented a revised ABN form as required under the Paperwork Reduction Act of 1995 (PRA). PRA requires that the notice is subject to comment and re-approval every 3 years.

b. The new form consolidates and replaces the general ABN (ABN-G) and laboratory-specific ABN (ABN-L) into one ABN form.

c. The acronym ABN now officially stands for “Advance Beneficiary Notice of Noncoverage” to more clearly convey the purpose of the notice.

d. Providers were required to use the new form as of March 1, 2009.

5. Key Features of the New ABN

a. Clinical laboratories will continue to have the opportunity to customize the new ABN form subject to the requirements set forth in CMS’ instructions. See www.cms.hhs.gov/BNI/02_ABNGABNL.asp.

b. The form still permits the use of the three usual reasons that laboratory services are denied:
i. Medicare does not pay for these tests for this condition (i.e., unacceptable ICD-9).

ii. Medicare does not pay for the testing as often as this (i.e., denied as too frequent).

iii. Medicare does not pay for experimental or research use testing.

c. Unlike the previous form, the new form includes a mandatory cost field where the notifier is required to make a good faith attempt to provide the cost of the item or service. If for some reason, the notifier is unable to provide a good faith estimate of projected costs, the notifier may indicate “not available.” But, this option is not to be used on a routine basis. Id.

d. The new form includes a new beneficiary option where an individual may choose to receive an item/service, and pay for it out-of-pocket, rather than have a claim submitted to Medicare.

   i. Option 2: “I want the tests listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.”

IV. Special Issues Affecting Genetic Testing and Emerging Technology

A. The Changing Landscape

1. As noted above, the mapping of the human genome has led to promising new types of testing.

2. Testing now allows labs to analyze tumor tissue and other specimens to determine likelihood of recurrence, source of disease and best types of therapies to be used.

3. Increased attention is being paid to “personalized medicine,” which looks at what drugs or therapies may be most beneficial for individuals.

4. Recently, increased marketing to individuals, offering various types of “direct to consumer” genetic testing.

5. This increasing attention has led to numerous issues related to what types of oversight is required and how these tests are billed and paid for.


B. Recent Activities Related to Oversight of LDTs
1. FDA position
   a. As noted above, in the ASR rule, FDA stated that no special rules were required for oversight of genetic testing.
   b. Many genetic tests arose as Laboratory Developed Tests, and are marketed by a single laboratory that performs the test “in house.”
   c. FDA has recently become more stringent in its view of what constitutes a Laboratory Developed Test.
      i. FDA has always taken the position it has jurisdiction over LDTs, but has traditionally applied enforcement discretion in this area.
      ii. In several letters, it has argued that certain tests do not qualify as LDTs.
      iii. In a letter to Exact Sciences, it alleged that a test being marketed by another laboratory was “designed, developed, validated and marketed by Exact Sciences.” As a result, the test was not a laboratory-developed test and FDA approval or clearance was necessary.
      iv. In September 2008, it took the same position with regard to the Ovasure test, which was allegedly designed, developed and validated by investigators at Yale, rather than by LabCorp, which was marketing the test.
      v. As discussed above, FDA has recently also issued Guidance that considerably narrows its view of what constitutes an ASR.
   
2. Although CMS previously proposed a new genetic testing subspecialty, it subsequently announced it would not create a genetic testing specialty under CLIA. Letter of Dennis G. Smith, Director, CMS Center for Medicaid and State Operations to Kathy Hudson, Director, Genetics and Public Policy Center (Aug. 15, 2007) (denying petition to create new genetics subspecialty in CLIA).

3. Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) Report on Genetic Testing
   a. Then-HHS Secretary Michael Leavitt directed SACGHS in March 2007 to investigate specific questions regarding the adequacy and transparency of the current oversight system for genetic testing.
   b. In response to this charge, SACGHS issued a draft report, “U.S. System of Genetic Testing: A Response to the Charge of the Secretary of HHS,” in November 2007. The draft report identified several gaps in the existing regulatory oversight system (relating to proficiency testing, clinical validity, transparency, clinical utility, and education of health care professionals) and made a number of recommendations to address these gaps and strengthen the
current system.

c. SACGHS issued the final version of this report in April 2008, finalizing many of the recommendations it had made in the draft report.

4. **Genentech Citizen Petition**

   a. Genentech Inc., a biotech company, filed a Citizen Petition with FDA on December 9, 2008, requesting a change in FDA policy on the regulation of *in vitro* diagnostic tests developed and performed by clinical laboratories. The Citizen Petition asked FDA to “require [that] all *in vitro* diagnostic tests intended for use in drug or biologic therapeutic decision making be held to the same scientific and regulatory standards,” including both LDTs and device manufacturers’ test kits.

   b. Based on the different ways the Citizen Petition formulates its requests of FDA, it is somewhat unclear whether the Petition is asking FDA to (1) assert jurisdiction over all LDTs and then determine how to regulate each of those LDTs based on a risk-classification analysis or (2) assert jurisdiction over only those LDTs used in drug or biologic therapeutic decision-making.

   c. Stakeholders have filed responses to the Citizen Petition, recognizing its potential significance for clinical laboratories and the *in vitro* diagnostic testing market.

   d. FDA has yet to issue a substantive response to the petition.

5. **New Development. ACLA Citizen Petition**

   a. In June 2013, the American Clinical Laboratory Association, a national trade association that represents clinical laboratories, filed its own Citizen’s Petition with the FDA.

   b. In that petition, ACLA challenged the authority of the FDA to regulate LDTs, arguing that Congress intended for laboratories to be regulated under CLIA, rather than the Food Drug and Cosmetic Act.

   c. ACLA requested that the FDA refrain from taking any action to regulate LDTs.

   d. The FDA has not yet issued a substantive response to the petition.

   a. In 2006, FDA issued a draft Guidance directed at a developing type of LDT, which it called “In Vitro Diagnostic Multivariate Index Assays” or IVDMIAs. After obtaining comments, it issued a second draft Guidance in July 2007. See www.FDA.gov/CDRH/OIVD/Guidance/1610.pdf

   b. FDA described IVDMIAs as devices that used an “interpretation function” to yield an index or score that would provide a patient-specific result.

      i. FDA was concerned that the “algorithm” used to obtain the result would often be non-transparent and not subject to independent verification.

      ii. FDA also stated it was concerned that patients might make critical decisions based on these tests, which it felt were not validated.

   c. FDA proposed requiring laboratories developing IVDMIAs to seek approval or clearance.

   d. The FDA intended to issue the Guidance, but failed to do so before the end of the Bush Administration. The FDA is now more focused on a broader approach to LDTs.

7. Recent FDA actions on LDTs

   a. On June 17, 2010, the FDA announced it was going to hold a 2-day meeting on the subject of “Oversight of Laboratory Developed Tests.” 75 Fed. Reg. 34463 (June 17, 2010).

   b. At that meeting, FDA officials noted that while they had decided some oversight of LDTs was necessary, they had not made any final decision about how to regulate them.

   c. FDA speakers also noted that the types of LDTs available today were far different than those that were contemplated initially.

   d. FDA also expressed its desire that any regulation of LDTs be risk-based, just as with other types of medical devices.

   e. Industry speakers also presented at the meeting, and many emphasized the difficulty of classifying LDTs based on risk and the fact that labs were already extensively regulated under CLIA.

   f. The FDA has yet to act in this area, although it continues to state that it has prepared several separate Guidance documents that will outline a general plan for the oversight of LDTs.
8. Direct to Consumer (DTC) testing

a. The FDA also took action against a plan by a clinical laboratory in San Diego to offer a direct to consumer genetic test, through Walgreens drug stores. In May 2010, the Washington Post wrote a story that Pathway Genomics, a laboratory in California, was planning to sell genetic tests directly to consumers.

b. While the Company argued that it was not required to seek FDA approval, because the testing was done in its own laboratory, FDA threatened to take action. As a result, the Company withdrew its plans to offer the test.

c. The FDA also sent letters to other companies offering DTC genetic testing, expressing concerns about the claims being made for the tests, including which medications would be best for an individual, given his genetic makeup, and the individual’s genetic predispositions for particular diseases.

d. Congress also held a hearing at which GAO testified about misleading test results received from several DTC companies. See, GAO, “Direct-to-Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices,” Rep. No. GAO-10-847T (July 22, 2010).

e. New Development. On November 22, 2013, the FDA sent a warning letter to 23andme, a company that offered genetic testing to patients. The FDA alleged that the tests offered by the company constituted a medical device, and that the company had failed to adequately validate the testing that it offered. Therefore, the company was directed to immediately stop offering the testing for sale. [link] The Company has complied with that request and currently only offers testing related to ancestry.

C. The “Date of Service” (DOS) Issue

1. Many of these new tests run into a unique billing issue that other tests do not face, related to bundling of the service with a prior hospital service.

2. The “Date of Service” issue involves peculiar interaction of two Medicare rules.

a. The laboratory Negotiated Rulemaking, discussed below, established that under Medicare rules the “date of service” of a lab test is the date the specimen was collected. See 66 Fed. Reg. at 58788, 58791 (Nov. 23, 1991) (42 C.F.R. § 414.510).

b. Many new tests are done on tumor tissue, fine needle aspirations and other specimens which are taken during hospital procedures.
c. If the specimen is later tested, even after the patient is discharged, the DOS is the date of the hospital stay.

d. Most tests performed for a hospital patient must be billed “under arrangements;” i.e., the lab must bill the service to the hospital which is responsible for billing/payment.

   i. Inpatient services are bundled into the DRG.

   ii. Outpatient services are billed by the hospital and now bundled into the APC.

e. The DOS issue

   i. When a test is done on a tumor or another type of specimen collected during a hospital stay, the DOS is the date of collection, when the patient was a hospital patient.

   ii. Thus, it was argued that even if the test was ordered and performed long after the patient left the hospital, the test still had to be bundled and billed to the hospital “under arrangements.”

   iii. Hospitals, however, frequently balked at paying the laboratory for the testing because the hospital was often not involved in the decision to order the testing and the patient was often long since discharged from the hospital.

f. The 14-day rule (42 C.F.R. § 414.510)

   i. To help resolve these issues, CMS adopted the 14-day rule.

   ii. For certain specimens, CMS held that if the test was ordered on a “stored specimen” at least 14 days following a patient’s discharge from the hospital, the DOS would be the date of performance.

      (A) The specimen had to be collected in the hospital.

      (B) It had to be medically inappropriate to have collected at the hospital in another way.

      (C) The tests did not guide hospital treatment.

   iii. Similar provisions were put in place for chemotherapy sensitivity testing, which was performed on live tissue. DOS would be date of performance if decision concerning which specific chemotherapeutic agents would be tested was made 14 days or more after discharge. 42 C.F.R. § 414.510(b)(3).
iv. Most hospitals still do not understand why they must pay for services ordered less than 14 days after discharge.

v. Because of issues related to the 14-day rule, PPACA included a demonstration project that would permit laboratories to bill directly for complex diagnostic tests, if they met certain requirements. The demonstration could not exceed a cost of $100 million. PPACA, § 3113.

D. **New Developments.** Payment Issues for New Technologies

1. In the past two years, there have been significant changes in the regulation and payment of Molecular Diagnostic tests, which include many commonly-performed genetic and similar tests used as part of the rapidly growing area of “personalized medicine.”

   a. These tests, many of which are used in the diagnosis and treatment of cancer, examine a patient’s genetic makeup and therefore are able to determine which types of treatment may be most effective.

   b. Many of these tests are performed as LDTs, although there are FDA-approved kits for some of them.

   c. As discussed below, there have been significant changes both in the coding of these tests and in the level of evidence that is required for coverage.

2. The Development of New CPT Codes

   a. Prior to 2013, most molecular diagnostic tests were billed using a process called “code stacking.”

      i. Each step in the process—DNA extraction, amplification, analysis—was billed separately, sometimes with more than one unit of service billed per step. The reimbursement for each step was then totaled to arrive at the total charge.

      ii. The problem with this approach is that only the steps were identified. The payor had no way to determine what type of analyte was actually being tested for. As a result, it was more difficult to judge the medical necessity of each test.

   b. In 2011, the CPT Editorial Panel announced that it was eliminating the “stacking codes” and was instead establishing over 100 different analyte specific codes, which would allow payors to better identify the specific test being performed.

   c. Most payors, including Medicare, did not adopt the new codes for 2012, but instead studied their impact for a year before implementing them, as discussed below.
3. The MolDx Program
   a. At the same time that the new CPT Codes were being developed, Palmetto, the Medicare Administrative Contractor for California and surrounding states, adopted a new payment process for Molecular Diagnostic tests, which it referred to as the “MolDx Program.”
   b. Palmetto adopted this Program because many of the laboratories doing this type of testing were located in California and subject to Palmetto’s jurisdiction.
   c. Under the MolDX Program, each laboratory offering a molecular diagnostic test would have to obtain a special billing code that identified the test. If a laboratory billed for a test without the code, the claim would be rejected. The codes could either be obtained from Palmetto itself (“PTI Code”) or from McKesson Health Solutions (“Z Code”). Palmetto has recently stated it will stop issuing PTI Codes at some point in the future, and is attempting to get labs to seek Z Codes instead.
   d. In addition, new molecular diagnostic tests would also have to go through a Technology Assessment overseen by Palmetto before they would be covered.
   e. Palmetto has not covered some molecular diagnostics tests either because it determined they were screening tests or because it determined there was insufficient evidence to support coverage. Although Noridian has taken over as the MAC in California, Palmetto continues to administer the MolDx Program there.
   f. Information on the MolDx Program can be found at http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCatHome/MolDx

4. The Gapfilling Process for New Molecular Diagnostic Tests
   a. When implementing the new molecular diagnostic CPT Codes, CMS faced two issues.
      i. First, there was a question of whether the new codes should be paid for as clinical laboratory tests, based on the clinical laboratory fee schedule, or as physician pathology services, based on the Physician Fee Schedule.
      ii. Second, if they were paid for as clinical laboratory tests, then should they be priced based on the crosswalking or gapfilling approach.
   b. CMS resolved each of these issues in the 2013 Final Physician Fee Schedule Rule. See 77 Fed. Reg. 68891, 68994 (Nov. 16, 2012).
      i. First, it determined that these tests should be considered clinical laboratory tests and payable on the clinical laboratory fee schedule. It
determined that many of these tests did not require interpretation by a physician, and therefore, were not appropriate for the Physician Fee Schedule. It did however establish a new “G Code” that could be used where the interpretation by a physician was medically necessary in a particular instance.

ii. Second, it determined that it would use the gapfilling process established in the regulations for pricing the tests, which meant that the contractors would be required to develop specific prices that would then be published by CMS.

c. The gapfilling process proceeded through most of 2013, although there were numerous complaints about the process from laboratories. Developments related to the gapfilling process can be found at the CMS website.  

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html

i. For the first four months of 2013, contractors developed prices for many of the molecular diagnostic codes. In some instances, the contractors simply used the prices established by Palmetto, as it was considered the contractor with the greatest expertise in this area.

ii. CMS published the carrier-specific prices on its website in May, 2013, which then initiated a 60 day comment period.

iii. CMS published the final carrier-specific prices on September 30, 2013, and allowed requests for reconsideration. The final prices represented a significant reduction from the old prices, established under “code stacking.”

iv. CMS issued the final prices on November 30, 2013, and also issued the medians of the contractor-specific prices. The median became the price for these codes effective January 1, 2014.

v. All of the medians published were the same as had been previously published in September, except for two codes. One of these codes, for BRCA 1/2 was significantly reduced for reasons that are unclear. CMS subsequently announced a special comment period, followed by a second period, with regard to the BRCA codes. It is not clear, currently, what action CMS will take with regard to this code.

5. The MAAA Codes

a. In addition to the molecular diagnostic codes, CMS has also struggled with how to price a related type of codes, the Molecular Assays with Algorithmic Analyses (MAAAs).
b. These codes often look at a variety of different variables to develop a score that predicts a patient’s likely response to a particular medical condition.

c. CMS originally took the position that it did not have the authority to cover these tests, because the algorithmic element was considered a calculation, which CMS does not usually pay for. However, in 2013, CMS determined that it would leave it up to the local contractors to determine whether or not to pay for the test.

V. The Impact of the Laboratory Neg/Reg

A. Background of Neg/Reg

1. The laboratory neg/reg was mandated by BBA'97, and arose from a concern about the differing LMRPs that had developed among the various carriers and FIs.

2. The BBA required CMS to convene a negotiated rulemaking to develop more uniform policies.

3. Eighteen laboratory groups, plus CMS, participated.


5. A proposed rule was published on March 20, 2000 (65 Fed. Reg. at 13083); the final rule was published on November 23, 2001 (66 Fed. Reg. at 58788).

B. Issues Addressed by the Final Rule

1. Medical conditions for which a test may be reasonable and necessary.

2. Information required with each claim.

3. Appropriate use of procedure codes.

4. Procedures for filing claims.

5. Documentation and record keeping requirements.

6. Limitations on frequency.

C. Key Issues Addressed by the Neg Reg

1. National coverage determinations

   a. The Rule establishes 23 separate national policies covering 63 procedure codes.
b. The policies establish uniform diagnosis codes, which will be accepted as demonstrating the medical necessity of the test ordered.

c. Contractors cannot have policies that conflict with the NCDs after the effective date, but they can supplement existing policies where the national policy is silent (e.g., frequency).

d. Usually, the NCD specifies the covered diagnosis codes, but the Blood Count NCD specifies that all codes are covered, except those listed.

e. Future changes were to be made either through a biennial review process or through the national coverage process.

2. Information required with each claim

a. Diagnosis codes

i. The final rule clarified that diagnosis codes were not required for every claim; only those where an LCD or NCD required it.

ii. As a result of the rules governing HIPAA transaction sets, however, most claims today have to include an ICD-9 code.

b. Date of service

i. The final rule mandated that the date of service (DOS) for a laboratory claim is the date the specimen was collected.

ii. For tests on stored specimens, DOS is the date the specimen was obtained from archives.

c. Physician signature

i. Final rule clarified that ordering physician does not have to sign laboratory requisitions.

ii. Laboratory must be able to show, however, that it was ordered by the treating physician.

iii. This issue is specifically covered by the Program Memorandum AB-02-030.

3. Procedure coding issues

a. Clarifies how to bill for repeat laboratory testing and testing from different sites, using “-59” and “-91” modifiers.

b. Use of screening in description of CPT codes does not always mean that the test is a screening, i.e., non-covered, service.
4. Claims filing procedures
   a. Narrative diagnosis issues
      i. Laboratories could translate narrative diagnoses into numerical ICD-9 codes.
      ii. CMS recognized in PM AB-02-030 that the narrative did not have to match exactly the description of the ICD-9.
      iii. Laboratories must use, however, the ICD-9 code submitted by the physician, unless the laboratory has written documentation from the physician authorizing the alteration of the code.

   b. Diagnosis code matching
      i. Contractors should examine all diagnosis codes submitted by the laboratory, in determining medical necessity.
      ii. The rule clarified that labs were not required to “match” or “point” to diagnosis codes, but PM AB-02-030 suggests this only applies on manual prepay review.
      iii. For screening services, the laboratory must either use a pointer; a GZ or GY modifier; or submit a separate claim for the screening services.

5. Documentation and recordkeeping
   a. The final rule established new regulations covering procedures for audits by carriers.
   b. Where a contractor sought additional information related to medical necessity, it must first seek information from the laboratory, which must submit information that it received from the ordering physician.
   c. If the contractor believes it needs information from the physician, then the contractor—not the laboratory—must request the information from the physician.
      i. This distinction was designed to address physician's privacy concerns.
      ii. If the contractor does not receive the information within a specified time period, it can deny the laboratory's claims as not medically necessary.
      iii. In CERT and RAC audits, contractors sometimes reportedly tried to require the laboratory to initially obtain the information from physicians.
   d. The laboratory is not precluded from also requesting additional information if necessary.
6. Frequency issues

a. Some of the new NCDs have very broad, and somewhat vague, frequency limitations (see, e.g., the Lipid NCD).

b. If a policy is silent on frequency, contractors can impose their own frequency limits, so long as the following requirements are met.

   i. Information must be published by CMS or the contractor stating what frequency is generally considered reasonable utilization.

   ii. The contractor is to consult with appropriate medical specialty and other organizations to develop frequency parameters.

c. The purpose of this rule was to end “secret” frequency screens.

VI. Key Compliance Issues for Clinical Laboratories

A. Suits Against Independent Clinical Laboratories

1. In the early 1990s, the government has brought several major cases against clinical laboratories, alleging fraud and abuse violations.

2. In the case against National Health Laboratories (NHL), the government alleged that the laboratory had induced physicians into ordering testing that was not medically necessary.

   a. The government alleged that NHL had added HDL and serum ferritin to its standard chemistry profile. These tests were then billed separately to the Medicare Program, in addition to the charge for the standard chemistry.

   b. The government alleged that it was significant that the price charged physicians for their non-Medicare patients was usually increased only nominally.

   c. As a result, according to the government, physicians were led to believe that it was permissible to order such testing, even though it was not medically necessary. The government alleged that these acts constituted violations of the federal False Claims Act.

   d. As a result, NHL paid $111 million to settle civil and criminal false claims allegations. The corporation and its CEO pleaded guilty to criminal violations.

   e. After the NHL case, the government sued other clinical laboratories alleging violations of the Federal False Claims Act and collected over $800 million dollars.
B. Suits Against Hospitals

1. The government also brought suit against hospitals that provided clinical laboratory testing under several different theories.

2. Operation Bad Bundle
   a. In Operation Bad Bundle, the government alleged that hospitals were overpaid because they had billed separately for certain tests that were ordered as “panels.”
   b. The government alleged that the hospitals should have bundled these tests together and been paid at a lower amount.
   c. Hospitals in many states received letters requesting repayment based on Operation Bad Bundle, although some of the requests were later withdrawn because the FI did not have accurate payment data.

3. DRG Window
   a. In addition, the government also sought repayment from hospitals that had violated the DRG payment window provision.
   b. Under this provision, all diagnostic services furnished to a Medicare beneficiary by the admitting hospital, or an entity wholly owned or operated by the hospital, within 3 days of the beneficiary's date of admission are considered inpatient services and thus covered by the hospital's DRG payment.
   c. The government has sought repayment from hospitals for violation of the DRG window rule.

C. The OIG's Compliance Guidances for Laboratories


2. The OIG's Compliance Program Guidance covers a variety of issues of importance to laboratories, including medical necessity, billing, use of standing orders, and pricing to physicians.

3. OIG's views on medical necessity
   a. In its compliance plans, the OIG took the position that even though laboratories do not make medical necessity determinations, they should advise physicians that Medicare will only pay for services that are medically necessary.
b. The OIG stated that it was important for laboratories to design requisitions in a manner that promoted “the conscious ordering of tests by physicians or other authorized individuals.” The form should also, according to the OIG, include a statement that Medicare does not cover routine screening tests. 63 Fed. Reg. at 45079.

c. According to the OIG, laboratories should also provide notices to physicians on an annual basis that include the following:

   i. Any national and local medical review policies for laboratory testing.

   ii. A statement that organ and disease panels will only be paid when all components are medically necessary.

   iii. A copy of the applicable Medicare fee schedule and a statement that Medicaid reimbursement will usually be equal to or less than that amount.

   iv. Additional information is required for “custom” profiles, i.e. profiles that are put together for the convenience of particular physicians.

d. The theory behind these disclosures is that they provide the physician with greater information in making a determination as to what testing is medically necessary.

e. The revision to the OIG's Compliance document included for the first time a discussion of the use of ABNs by laboratories.

   i. Where it is likely that a test will not be covered by Medicare, the laboratory may request that the beneficiary sign an ABN indicating the beneficiary's consent to be financially liable if payment is denied.

   ii. The laboratory may ask the ordering physician to obtain the ABN, but it is the laboratory's responsibility to produce it, when necessary.

   iii. According to the OIG, routine use of ABNs, or merely stating that denial of payment is possible, or that it is impossible to know when payment will be denied, is forbidden. 63 Fed. Reg. at 45080.

   iv. The ABN must be in writing, must identify a specific service, and must explain the reasons that payment is believed likely to be denied. Id.

f. Laboratories are also to monitor test ordering to ensure that test ordering is not excessive. The Compliance Plans set out methods for performing this analysis. 63 Fed. Reg. at 45080.

4. OIG's View on Billing Properly
a. The OIG believes that laboratories should take steps to ensure that the CPT/HCPCS code provided accurately describes the service furnished.

b. Laboratories should not alter the physician's order in any way, either increasing or decreasing the number of services performed. *Id.* at 45080.

c. Selection of ICD-9-CM codes.

   i. As discussed above, Medicare contractors often specify the particular diagnosis codes for which a test will be covered.

   ii. According to the OIG, laboratories should ensure that the "lab can support tests billed to Medicare with documentation from the physician ordering the test" or other authorized person. *Id.* at 45080.

   iii. Laboratories should not, according to the OIG,

      (A) Use information provided by the physician from earlier dates of service (other than standing orders).

      (B) Create diagnosis information that has triggered reimbursement in the past.

      (C) Use computer programs that automatically insert diagnosis codes without receipt from the ordering physician or other authorized person.

      (D) Make up diagnosis information.

   iv. Laboratories may, however:

      (A) Contact the ordering physician or other authorized person to obtain information if it was not provided.

      (B) Accurately translate narrative diagnoses obtained from the physician or other authorized person. *Id.*

d. Ambiguous/insufficient orders. Where a test order is ambiguous, laboratories should not bill for testing until they have verified the tests that the physician actually wished to order. Similarly, where the test cannot be performed because of an accident or insufficient specimen, then the laboratory may not bill for the testing. *Id.* at 45080-81.

e. Calculations. Laboratories should not bill for calculations and the underlying tests performed to obtain such calculations. *Id* at 45081.

f. Reflex testing. In its revised Compliance Program Guidance, the OIG included a discussion of reflex testing. According to the OIG,
laboratories should design their requisitions to only allow for reflex testing when necessary. Reflex testing is testing performed when initial results are positive or indicate the need for further testing. *Id.* at 45081.

5. OIG's views on standing orders
   a. In the revised Compliance Program Guidance, the OIG stated that the use of standing orders was “discouraged,” because of concern about abuse. *Id.* at 45081.
   b. The OIG also suggested that laboratories periodically review standing orders with facilities. It specifically noted that laboratories furnishing testing to ESRD facilities should reconfirm these orders at least annually, with the facility.

6. Prices charged to physicians
   a. In the revised Compliance Program Guidance, the OIG stated that physicians should not provide inducements to obtain a physician's non-Medicare testing.
   b. The OIG stated that it would be an inducement to charge physicians a price below fair market value for their non-federal health care program testing. *Id.* at 45081.

7. Other provisions of the Compliance Program Guidance mirror those found in the other compliance plans concerning the structure of compliance programs.

D. The OIG's Fraud Alert for Laboratory Services
   1. In 1994, the OIG also issued a special Fraud Alert dealing with laboratory practices that also discussed particular issues of concern to laboratories. 59 Fed. Reg. at 65377 (Dec. 19, 1994).
   2. That Fraud Alert focused on the following four areas:
      a. Provision of phlebotomy services
         i. The OIG stated that it is *not* an unlawful inducement for a laboratory to place an employee in a physician's office for the purpose of drawing specimens sent to the lab. The OIG stated that the anti-kickback law might be implicated, however, where the phlebotomist performed additional tasks that would usually be done by physician office staff, such as nursing functions, clerical services or doing testing in the physician own laboratory.
         ii. The OIG also noted that the mere existence of a contract between the laboratory and the physician or other health care provider that prohibits the
phlebotomist from performing such duties does not resolve the issue. The laboratory must, according to the OIG, monitor the phlebotomist to ensure the contractual provision is enforced.

b. Composite rate services for ESRD patients

i. Laboratory services provided to ESRD patients are reimbursed on two separate bases. Certain routine laboratory services are included in the “composite rate” payment made to the ESRD facility by the Medicare Program. Laboratories typically bill the ESRD facility for those services on a discounted or capitated basis. On the other hand, nonroutine laboratory services performed for ESRD patients are billed by the laboratory directly to the Medicare program, and reimbursed at the usual fee schedule amount.

ii. The OIG expressed concern that some laboratories employed a practice of billing the facility at a low rate of $1 or $2 for all the composite rate testing furnished an ESRD patient during a month. The OIG stated the laboratory could only do this because it could then bill the non-composite rate testing at the usual, higher Medicare fee schedule price. The OIG stated that laboratories should not be providing the testing services covered by the composite rate at less than fair market value.

c. Waiver of charges to managed care patients. The OIG noted that sometimes a health care plan will require physicians to utilize a particular laboratory for all the testing covered by the plan. If the physician usually uses a different laboratory, that laboratory may wish to do the work for free, out of a concern that otherwise it will lose all the physician's business. The lawfulness of such arrangements, according to the OIG, depends on whether the physician's arrangement with the health care plan rewards the physician for keeping utilization at particular levels. In that case, the physician might enjoy a financial benefit from the laboratory's agreement not to charge for the services.

d. Other services. The OIG also highlighted certain other services that it said might raise questions. These included:

i. Free pick up and disposal of biohazardous waste, such as sharps, unrelated to the collection of specimens.

ii. Provision of computers or fax machines, unless the equipment is integral to, and used exclusively for, the laboratory's work.

iii. Provision of free “professional courtesy” testing to physicians.
E. Advisory Opinion 99-13

1. In a 1999 Advisory Opinion, the OIG looked at instances in which a laboratory gave a discount, which the requester stipulated was “below cost,” to physicians on their private pay work, even though it billed Medicare at its usual charges. In its Opinion, the OIG concluded that the arrangement could violate both the anti-kickback law and the substantially in excess exclusion provision. Advisory Opinion, 99-13 (Nov. 30, 1999).

2. Facts of the opinion
   a. The requester was a laboratory that provided clinical and anatomical pathology services to hospitals and physicians in private practice.
   b. When billing physicians, the laboratory billed physicians at a discount off its usual prices, which reflected in part the cost savings that it realized by being able to bill physicians on a monthly basis. It was stipulated that to match the prices of competitors, however, the laboratory would sometimes give a discount that was “below the actual cost of providing the pathology services.”
   c. For federal health care work, such as Medicare or Medicaid, the laboratory billed its usual charges to the programs, although it would be paid at a lower rate than its charges.
   d. It was stipulated that, under this arrangement, the laboratory's profit margin for non-federal health care work would be less than its profit margin on the Medicare and Medicaid work.
   e. The discount was not conditioned on physicians agreeing to send their federal work to the laboratory; however, it was assumed that physicians receiving the discount would prefer to send all of their work to a single laboratory.

3. The legal analysis
   a. The anti-kickback analysis
      i. The OIG noted that the arrangement was not eligible for the discount safe harbor, because the discount being given to the physicians was not being given to Medicare or Medicaid. The OIG noted:

      Neither Medicare nor Medicaid benefits from the discount; to the contrary, Medicare and Medicaid may, in effect, subsidize the other payor's discounted rates. Moreover, laboratories may have an incentive to engage in abusive billing practices to recoup losses on the discounted business.
ii. The OIG determined that the discount might in fact involve unlawful remuneration under the anti-kickback law, because a “nexus may exist between the discount to the physicians” for private pay work and referrals of Federal health care program business. The OIG pointed to three factors in support of this view. They were:

(A) Physicians are in a position to direct a significant portion of Medicare business to the laboratory, which was not covered by the discount.

(B) The arrangement was beneficial both to the physicians, who earned a larger profit on the private pay work, and the laboratory, which secured more Medicare and Medicaid business.

(C) It was recognized that physicians receiving the discount would refer federal business to the laboratory as a matter of convenience.

iii. The OIG noted that in determining whether the discount was unlawful, it would look at whether there was evidence that the discount was not commercially reasonable, unless the laboratory also received other, non-discounted business.

iv. The OIG suggested that the factors that would support that conclusion were the following:

(A) Prices were below the laboratory's cost; or

(B) If the laboratory offered a smaller discount to physicians with equal volume, but no Medicare work.

v. In defining “below cost” the OIG used “average total cost,” which it defined as “the total of all costs (including labor, overhead, equipment, etc.) divided by the total number of laboratory tests.”

b. The substantially in excess issue

i. Under the fraud and abuse laws, a provider may be excluded from participation in federal health programs, if its charges to Medicare or Medicaid are “substantially in excess of its usual charges.”

ii. The OIG said that in determining usual charges it would look at amounts charged to nonfederal payors, including physicians and the amounts that the laboratory contractually agreed to accept from other payors.

iii. The OIG subsequently tried on several occasions to define what conduct would violate the “substantially in excess” provisions but withdrew its
last proposal. See 72 Fed. Reg. 33430 (June 18, 2007).

4. Follow-up letter

a. On April 26, 2000, partly in response to concerns from the laboratory community, the OIG issued another letter clarifying its position. See http://www.oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm.

b. The requester of the letter asked whether Advisory Opinion 99-13 required laboratories to raise their charges to meet or exceed Medicare's fee schedule.

c. The OIG's response stated that discounting arrangements below the benchmarks discussed in Advisory 99-13 were not “illegal per se,” but only suspect. The letter stated that the OIG recognized “that there are reasons why a company might agree to sell services below its average fully loaded costs.” However, the OIG believed that where such arrangements were coupled with the referral of Medicare business, they merited close scrutiny.

d. The letter also discussed the OIG's interpretation of the substantially in excess provision.

i. According to the OIG, this section is "not a blanket prohibition on discounts to private pay customers."

ii. The letter stated that the substantially in excess provision:

addresses a much narrower issue: tiered pricing structures that set one price for Medicare or Medicaid and a substantially lower price for most other customers. Given the statutory language, we do not believe that the section 1128(b)(6)(A) is implicated unless a provider’s charge to Medicare is substantially in excess of its median non-Medicare/Medicaid charge. In other words, a provider need not even worry about section 1128(b)(6)(A), unless it is discounting close to half of its non-Medicare/Medicaid business.

iii. The letter also notes there is an explicit exemption in the law if the Secretary finds good cause for the differences.

F. Stark Self-Referral Issues

1. Diagnostic laboratory services are covered by the Stark self-referral provisions, which prohibit physicians from referring Medicare and Medicaid patients to entities with which they have a financial relationship. Soc. Sec. Act, § 1877. A full analysis of issues raised by Stark is beyond the scope of this presentation.

2. Laboratory services were actually covered by the initial version of Stark, usually referred to as “Stark I,” which was passed in 1989.
3. The following areas in the Stark regulations may be of particular interest to laboratories.

a. The regulation clarifies the pathologist referral exemption, which permits pathologists to refer specimens to a laboratory with which they have a financial arrangement, so long as the procedure is performed by or under the supervision of the pathologist, pursuant to a “consultation” requested by another physician. 66 Fed. Reg. at 873 (2001). 42 C.F.R. § 411.351 (definition of “referral”).

b. Shared laboratories are not explicitly permitted under the new rules, but CMS states that changes to the requirements for the “In Office Ancillary Services” exception may permit shared laboratory facilities to be exempt. See id. at 892-93.

c. Only certain supplies can be furnished by a lab to a referring physician without creating a compensation arrangement under the law. It notes that items of low value, such as single-use needles, vials and specimen cups are permitted, but reusable items, such as biopsy needles, snares and reusable aspiration and injection needles, are not. Furthermore, gloves, while used in the specimen collection process, are not permitted, because they may be used for so many other purposes in a physician's office. Finally, the rule states that the laboratory or the physician should be able to demonstrate that the number of permitted items and supplies were appropriate for the level of referrals expected. Id. at 947-48.

G. New Development. EHR Donations

1. There is a safe harbor under the antikickback law and a new exception under the Stark law, both of which permit the donation of certain electronic health records software to physicians and other health care providers.

2. Those provisions were recently extended until December 31, 2021. However, at the request of most participants in the laboratory industry, laboratories were specifically excluded from the types of entities that may donate EHR items and services, because of concern about the abuse that had taken place. See 78 Fed. Reg. 78751, 79202 (Dec. 27, 2013).