This handout is provided for informational purposes only and does not constitute legal or professional advice. The content is intended to be general in nature and may not apply to your specific situation. No attorney-client or other professional relationship is created by this material. You should consult with a qualified professional for advice tailored to your circumstances.

Thank you for attending the recent webinar, *Navigating Regulatory Challenges: Recent Enforcement, Risk Mitigation, and FDA Developments for Clinical Laboratories*, held on April 3, 2025.

We'd like to extend our sincere thanks to all participants for attending the session and for the thoughtful questions submitted throughout the presentation.

Special thanks to **TELCOR** for sponsoring the event and to **Dark Daily** for hosting. We are also grateful to our presenters, Caitlin Forsyth and Darla Wanitschke, for sharing their valuable insights.

A full recording of the session along with the slides can be accessed here:
https://go.telcor.com/navigating-regulatory-challenges

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QUESTIONS & RESPONSES

1. **Can you speak to the use of reflex tests in the world of using presumptive testing then allowing a reference lab to reflex to definitive testing based on their algorithm?**

   Medicare Administrative Contractors (MACs) and commercial health plans have varying policies on coverage of reflex testing.

   In general, the ordering provider – not a laboratory algorithm – should be the one making the determination about which definitive tests are appropriate based on the results of the presumptive screen and the patient's individual circumstances.

   Noridian, for example, permits Medicare coverage for reflex testing by reference laboratories in the following circumstances:

   - *To verify a presumptive positive UDT using definitive UDT (GC-MS or LCMS/MS) before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or*

- *To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.*[1]

Aetna's coverage policy on drug testing also covers reflex testing by reference laboratories in the same circumstances enumerated in the Noridian policy:

> *Because reference laboratories do not have access to patient-specific data, it is considered medically necessary for a reference lab to reflex to a definitive test before reporting a positive presumptive result to the clinician. It is also considered medically necessary for a reference lab to reflex to a definitive test to confirm the absence of prescribed medications when a negative presumptive result is obtained for a prescribed medication listed by the ordering physician.*[2]

2. If the physician has a lab, can they reference an IRL and bill for those services while their instrument is being repaired? Does the 30 or 40% reference out rule apply?

Payers (government payers and commercial health plans) have varying policies on whether a laboratory can bill for testing the laboratory does not itself perform. Medicare permits a referring laboratory to bill for testing a reference laboratory performed so long as the requirements of the 70/30 rule are met. That is, "the referring laboratory does not refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year."[3]

United Healthcare's billing policy, on the other hand, expressly states:

> *You may only bill for services that you or your staff perform. Pass-through billing is not permitted and may not be billed to our members.*[4]

Regence's policy on billing for reference testing permits only independent clinical laboratories to bill for testing performed by a reference laboratory:

> *Our Health Plan does not allow pass-through billing for laboratory services.*

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[1] Local Coverage Determination L35006, Noridian, available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=35006&ver=119
[2] Drug Testing in Pain Management and Substance Use Disorder Treatment, Aetna, available at: https://www.aetna.com/cpb/medical/data/900_999/0965.html
[3] Medicare Claims Processing Manual, Chapter 16, Section 40.1, available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf
[4] Laboratory Services Policy, UnitedHealthcare, available at: https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-Laboratory-Services-Policy.pdf

> *Laboratory services identified as being pass-through billing, without the use of modifier 90, are subject to review.*
>
> *Laboratory services billed with modifier 90 will only be reimbursable when billed by independent laboratories, unless State, Federal or Centers for Medicare & Medicaid Services (CMS) contracts and/or requirements indicate otherwise.*
>
> *Only independent clinical laboratories can refer laboratory services to another laboratory.*[5]

Regence might take the position that a physician office laboratory is *not* an independent laboratory.

3. **If someone is supposed to be taking a drug, and the drug test comes back presumptive negative, should that reflex to definitive to look for sub-analytes of the expected drug?**

Please see our answer to question number 1. However, in short, some payers do permit (i.e., will cover/reimburse for) reflex testing performed to confirm a negative presumptive result for a prescribed medication.

4. **Can the laboratory pay one of the staff members of the physician's office as a 1099 to perform functions that are specific to the services offered by that lab, i.e., specimen collection, document assembly, prior authorizations?**

Arrangements like these present risk under the federal Anti-Kickback Statute, the federal Physician Self-Referral (Stark) Law, and the Eliminating Kickbacks in Recovery Act (EKRA). Structuring the arrangement to make payment to the staff member directly, instead of the referring provider (or the referring provider's practice), does not meaningfully change the risk profile.

In 2014, the federal Office of Inspector General (OIG) for the Department of Health and Human Services issued a "Special Fraud Alert" (SFA) highlighting the AKS risks presented by laboratories paying physicians for specimen collection services, stating in relevant part:

> *The anti-kickback statute is implicated when a clinical laboratory pays a physician for services. Whether an actual violation of the statute occurs depends on the intent of the parties—the antikickback statute prohibits the knowing and willful payment of such amounts if even one purpose of the payment is to induce or reward referrals of Federal health care program*

[5] Modifier 90; Reference (Outside) Laboratory, Regence, available at: https://www.regence.com/provider/library/policies-guidelines/reimbursement-policy/modifier-90

> *business. This is true regardless of whether the payment is fair market value for services rendered. The probability that a payment is for an illegitimate purpose is increased, however, if a payment exceeds fair market value or if it is for a service for which the physician is paid by a third party, including Medicare.*
>
> *[…]*
>
> *Characteristics of a Specimen Processing Arrangement that may be evidence of such unlawful purpose include, but are not limited to, the following:*
>
> - *Payment exceeds fair market value for services actually rendered by the party receiving the payment. Payment is for services for which payment is also made by a third party, such as Medicare.*
> - *Payment is made directly to the ordering physician rather than to the ordering physician's group practice, which may bear the cost of collecting and processing the specimen.*
> - *Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals.*
> - *Payment is offered on the condition that the physician order either a specified volume or type of tests or test panel, especially if the panel includes duplicative tests (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.*
> - *Payment is made to the physician or the physician's group practice, despite the fact that the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party.*[6]

OIG Advisory Opinions 05-08 and 22-09 also address laboratories' arrangements to pay referring providers for specimen collection services.[7]

5. Is offering a discounted cash pay rate for services for the physician's uninsured patients considered a violation of AKS? For example, if a test's Medicare reimbursement is $100, but the lab offers it for $50 for self-pay patients.

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[6] Special Fraud Alert: Laboratory Payments to Referring Physicians, OIG, available at: https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf

[7] OIG Advisory Opinion 05-08, available at: https://oig.hhs.gov/documents/advisory-opinions/499/AO-05-08.pdf; OIG Advisory Opinion 22-09, available at: https://oig.hhs.gov/documents/advisory-opinions/1031/AO-22-09.pdf

Offering discounted rates to self-pay patients is generally permissible, but such a practice should be carefully undertaken. Regulators may scrutinize laboratories' proposals to discount testing for self-pay patients to secure referrals of other "full cost" tests. OIG Advisory Opinion 15-04 addresses some of the risks presented by laboratories offering free or discounted testing.[8]

Laboratories should develop and implement written policies on setting prices for cash-pay testing, consistently implement such policy, and consult legal counsel to ensure compliance with applicable regulations.

6. **I have a particular question about molecular billing in non-MolDx jurisdictions (NOVITAS & FCSO). There appears to be a conflict on the appropriate method of billing out molecular claims, claims such as UTI, RPP, GI, STI, etc. The AMA supports the billing of multiple units of 87798, while Medicare provider educational pieces recommend the use of a single CPT single unit of service for these multiplex tests. Can you provide any guidance as to what you are seeing in terms of successful payments, denials, clawbacks? Is one method the preferred way?**

   There continues to be ambiguity in the appropriate billing methodology for multiplex molecular panels in non-MolDx jurisdictions such as those overseen by NOVITAS and FCSO. While the AMA supports the use of multiple units of CPT code 87798 to reflect the number of individual targets tested, educational guidance from Medicare Administrative Contractors (MACs) in these jurisdictions often advises providers to bill a single unit of service using a comprehensive code such as 87801 when applicable.

   In practice, some laboratories have reported reimbursement success from non-MolDx jurisdictions when billing certain recognized Group 8 CPT codes (e.g., 87481, 87640, 87653) in conjunction with multiple units of 87798. However, reimbursement practices are not always consistent, particularly with commercial payers, and there have been instances of claim denials, post-payment audits, and recoupments.

   Given the variability in payer policy interpretation and enforcement, laboratories are strongly advised to consult directly with the applicable payer or MAC to confirm current billing expectations. Where possible, securing written guidance or payer policy documentation may help mitigate audit risk. Laboratories should also maintain thorough documentation of medical necessity and clearly link test components to reported codes to support billing practices.

[8] OIG Advisory Opinion No. 15-04, available at: https://oig.hhs.gov/documents/advisory-opinions/693/AO-15-04.pdf