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Labs to HHS: Since We Can't COVID-19 Test Everyone, Let Us Prioritize the Symptomatic

Labs continue to lack the resources necessary to meet the demands for timely COVID-19 testing. In July, industry groups called on the White House to take control and resolve, or at least allay the reagent shortages and supply chain bottlenecks that have dogged testing efforts since the crisis began (See, *National Intelligence Report*, July 20, 2020). But now that seems to be off the table with labs being told not to expect any relief on the supplies front for at least the remainder of the year. So, the industry is moving to Plan B: figuring out how to prioritize the testing resources it does have available until the supplies challenges are resolved. And they're once more asking the Administration for help.

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2021 Medicare Physician Fee Schedule: Slashes Lab Reimbursements 5% but Provides Some PAMA Relief

On August 3, CMS released the proposed Medicare Physician Fee Schedule (PFS) rule for 2021. Bottom line on top: The agency is slashing lab reimbursement rates. Here are the four key takeaways for labs. Note that the deadline to comment is October 5.

1. Overall Physician Payment Rates

CMS is proposing to reduce the conversion factor it uses to calculate the PFS rate from $36.09 to $32.26. This whopping 10.6 percent cut is necessary because CMS is significantly increasing E/M code reimbursement rates in 2021 and, by law, the agency is required to maintain budget neutrality by implementing decreases to offset increases.

2. Impact on Labs and Pathologists

The reduced conversion factor and other proposed policy changes will reduce overall payments to independent labs by approximately

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Labs to HHS: Since We Can't COVID-19 Test Everyone, Let Us Prioritize the Symptomatic, *from page 1*

Labs to HHS: Help Us Prioritize Testing Services

On August 11, seven healthcare organizations sent a letter to the US Department of Health and Human Services (HHS) asking the agency to update COVID-19 testing prioritization guidelines. "We are increasingly concerned about the serious strains being placed on testing services for COVID-19, the impact those strains have on our ability to provide timely medical care to our patients, and ultimately on our ability to contain the spread of this dangerous virus," the letter begins.

"Without improvement in available supplies, we simply do not have the resources to meet the huge demand for testing." Accordingly—and in bold face—the letter calls on the Administration to update its testing prioritization guidelines.

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Prioritize the Sick Over the Asymptomatic

Specifically, the organizations want clarification that for as long as there aren't enough supplies to test everyone, prioritization should be placed on those with medically indicated need for COVID-19 testing, including persons who are symptomatic, have known exposures to the virus and/or in need of pre-procedure testing.

While acknowledging society's need for broad testing for performing medical surveillance and ensuring safe reopening, the letter recommends that testing of asymptomatic individuals without exposure to COVID-19 be assigned a lower priority. "During critical public health emergencies, limited testing resources must first be directed towards those who need them most—those at immediate risk of infection and serious illness," urges the letter.

Takeaway

And, so it's come to this. After months of warnings, finger points and political claims, the clinical leaders of the lab industry are making it plain that they don't have the supplies to test everyone who wants to be tested and that the problems will continue until at least through the end of the year. Having failed to resolve the supplies shortage, it's now up to the powers that be to clarify who should get tested so that physicians and labs know how to make the right "Sophie's Choice" testing decisions they face in the months ahead.

(Editor's Note: Sophie's Choice is a 1979 William Styron novel in which the protagonist, a newly arrived World War Two death camp inmate, must choose which of her two children to send directly to the gas chambers and which to allow to survive.)

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The 7 Signatories

The signatories to the HHS letter requesting COVID-19 test prioritization guidance was signed by seven of the most powerful and respected medical and lab organizations in the US, including:

- The American Medical Association
- The American College of Medical Genetics and Genomics
- The American Society for Clinical Pathology
- The Association for Molecular Pathology
- The Association of Pathology Chairs
- The College of American Pathologists
- The Infectious Diseases Society of America

LDTs: FDA Breaks New Ground by Authorizing SARS-CoV-2 Tests for Sample Pooling

It's not uncommon for the FDA to revise the Emergency Use Authorization (EUA) for a particular diagnostics test to permit a new clinical use. In most cases, these expansions don't even get an official announcement. But on July 18, the agency saw fit to pull out all of the stops and officially announce an EUA that was both unprecedented and significant because it allowed for COVID-19 testing on pooled samples.

The Quest SARS-CoV-2 Test

The distinction of being the first test approved for pooled testing went to Quest Diagnostics' SARS-CoV-2 RNA test, which initially received EUA back in March. The expanded EUA allows the test to be used with pooled upper respiratory specimens in sample pools comprised of four individuals. "The new update allows Quest to test 3,600 more tests per day," noted **Timothy Stenzel**, director of the Office of In Vitro Diagnostics and Radiological Health at the FDA's Center for Devices and Radiological Health during a recent agency "town hall" briefing, "and if you add pooling on top of that. . . they can substantially increase the throughput."

Use of pooling takes on particular significance during the current COVID-19 testing supplies shortage because it enables testing labs to get the most out of their limited testing resources. But there's also a tradeoff.

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FDA Breaks New Ground by Authorizing SARS-CoV-2 Tests for Sample Pooling, *from page 3*

Pooling dilutes the nucleic acids produced by the SARS-CoV-2 virus, thereby creating the risk of false negatives. To secure the EUA expansion for the SARS-CoV-2 RNA test, Quest provided the FDA clinical data showing that none of a total 3,091 specimens from a population with a prevalence rate of 1 to 10 percent would have come back falsely negative had the specimens been pooled. Quest immediately began performing pooled sampling testing with the assay starting with its laboratories in Marlborough, MA, and Chantilly, VA.

Takeaway

Less than a week later, the FDA announced that LabCorp's COVID-19 RT-PCR Test had received the second expanded EUA for pooled SARS-CoV-2 testing. The LabCorp test is authorized for human specimen collection at home using the Pixel by LabCorp or other home sample collection kits authorized for use with LabCorp's test, or by a healthcare provider. However, only samples collected by healthcare providers may be pooled using the test, the FDA noted. The expanded EUA also allows the test to be used for testing the broad population under the FDA's new asymptomatic screening guidance, making it the first SARS-CoV-2 test to gain that distinction. As of August 13, a total of four COVID-19 tests have received EUA for sample pooling.

COVID-19 Tests Receiving EUA Authorization for Sample Pooling

EUA Date	Manufacturer	Product
July 18	Quest Diagnostics	SARS-CoV-2 RNA test EUA expanded for pool sampling use
July 24	LabCorp	EUA for COVID-19 RT-PCR test and home collection kit reissued for sample pooling and use on asymptomatic patients
July 31	University of California San Diego Health	UCSD RC SARS-CoV-2 Assay gets EUA for sample pooling
Aug. 3	Poplar Healthcare	Poplar SARS-CoV-2 TMA Pooling assay gets EUA for sample pooling

FDA Watch: January 1, 2021 Is D-Day for Hospital Pricing Transparency

It appears to be full speed ahead for hospital price transparency. The controversial effort to make hospitals divulge information about their healthcare pricing, including lab procedures, is very much a part of CMS' proposed hospital prospective payment system proposed rule for 2021.

CMS' Push for Price Transparency

In November 2019, CMS published a final rule requiring hospitals to publish their chargemasters online for consumers. The agency made it clear that this would be the first of potentially many initiatives geared toward increasing transparency around hospital and other provider fees. The goal of all of these changes is to improve the ease and accuracy with which consumers can understand the expected out-of-pocket expenditures for patient care.

The rules, which are contained in FY 2021 Proposed Rule CMS-1735-P, aka, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals," take effect on January 1, 2021, one year later than initially proposed.

What the New Transparency Rules Require

The new rules require hospitals to make real negotiated prices known to patients. More precisely, they must make public their "standard charges" for both gross charges and payer-specific negotiated charges for all items and services.

Pricing information must also be available on the Internet in a machine-readable file and include information such as common billing or accounting codes used by the hospital, along with a description of the particular item or service. The pricing information must be presented in a "consumer friendly" way and include payer-specific negotiated charges for common "shoppable" services.

3 Things You Need to Know to Ensure Proper Implementation

Hospital labs need to start taking steps to implement the new rules when they take effect on January 1. To do that, there are three things you need to know:

1. What "Shoppable Services" Means

The "shoppable services" for which you must provide pricing information are those that can be scheduled by a health care consumer in advance,

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theoretically in the interest of shopping out the best price or deal. That would, of course, include most lab tests, as well as x-rays, outpatient visits, imaging tests and bundled services like pre- and post-delivery care and cesarean deliveries.

Hospitals would have to display negotiated charges for at least 300 services, including 70 selected by the CMS and 230 selected by the hospitals. The services could include both inpatient and outpatient procedures and affect all patients, not just Medicare beneficiaries. (CMS cites the Public Health Service Act as the source of its authority to impose these pricing requirements on hospitals not in Medicare.)

2. What "Consumer-Friendly" Means

Simply disclosing hospital charge information isn't enough. The disclosure must also be "consumer-friendly," i.e., made public in a prominent location online (or in written form upon request) that's easily accessible, without barriers and searchable. Product and service descriptions must also be in "plain language" with the shoppable service charges displayed and grouped with charges for any ancillary services the hospital customarily provides with the primary shoppable service. Hospitals also have to update their posted pricing information at least once a year.

3. What the Transparency Rules Don't Require

Finally, keep in mind that the CMS transparency rules short of requiring hospitals to post *patient-specific* price information, e.g., information showing particular patients where they are in meeting their deductibles.

The Pushback

While largely sympathetic with its objectives, hospital and health care industry groups have opposed the CMS transparency plan from the onset. According to American Hospital Association (AHA) President **Rick Pollack**, requiring hospitals to post negotiated rates "could seriously limit the choices available to patients in the private market and fuel anticompetitive behavior among commercial health insurers in an already highly concentrated insurance industry."

There's also concern about the potential costs and risks associated with the transparency rules, particularly in terms of patient relations and expectations. Standard charges, for example, are based on customary care and don't take into account emergency or acute situations. In other words, standard pricing assumes a best-case scenario which doesn't always prove to be realistic. This puts labs in a ticklish position when actual patient charges end up being higher than the previously quoted prices. The potential result is damage to not only customer relations but also the trust on which the patient relationship is based.

Takeaway

The AHA has also challenged the constitutionality of the transparency plan. But in June 2020, a federal district court sided with CMS and tossed the case. As a result, barring another delay, January 1, 2021 will be D-Day for pricing transparency. And the stakes are high. The agency also said it wants to enforce the price transparency requirements by monitoring, auditing and imposing civil monetary penalties of up to $300 a day and more than $100,000 per year against hospitals that don't comply.

Stark Law: CMS Proposes to Peel Back Restrictions on Physician Owned Hospital Expansions

From the onset, the Administration has assigned a high priority to loosening Stark Law and Antikickback Statute (AKS) restrictions. And now CMS has floated two new proposals allowing for greater expansion of physician-owned hospitals (POHs). Here's a quick briefing.

POHs & the 'Whole Hospital' Exceptions

The Stark Law bans physicians from referring Medicare patients to entities in which they or a family member hold a financial interest. However, the "whole hospital" exception allows physicians to make referrals to such hospitals under two conditions:

- They're authorized to perform services at that hospital; and
- Their financial interest is in the whole hospital, as opposed to a specific department or subdivision like the lab.

Section 6001 Restrictions

Savvy physicians took advantage of the rules by investing in POHs providing specialized services, basically freestanding versions of hospital divisions established to meet the whole hospital exception. The ironic effect was to promote growth of an industry fueled by the self-referrals that the Stark was designed to prevent. Sure enough, Congress investigated and while deciding to leave the whole hospital exception intact, adopted new restrictions in 2010, i.e., Section 6001 of the Affordable Care Act (ACA), to prevent further abuses.

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Stark Law: CMS Proposes to Peel Back Restrictions on Physician Owned Hospital Expansions, *from page 7*

Other Section 6001 Restrictions on POHs

In addition to limiting expansion of existing POHs, the Section 6001 changes to "whole hospital" exception rules:

- Prohibit the establishment of new POHs;
- Require POHs to report to HHS, disclose to their patients and post on their websites and public ads who their investors are and what terms of investment they have; and
- Cap the aggregate value of investments owned by physicians (as opposed to nonphysicians) at 2010 levels.

Relaxation of Limits on POH Expansions

The new proposal, which is part of the 2021 Outpatient Prospective Payment System (OPPS) Rule, seeks to peel back some of the Section 6001 restrictions, specifically the rules banning existing POHs from increasing the number of operating rooms, procedure rooms and beds without first getting an exception from CMS. The agency is proposing two changes:

1. Exempt "High-Medicaid" Facilities from 2-Year Request Window

Current Rule: Facilities are allowed to request a CMS exception to expand only once every two years.

Proposed Change: CMS would allow "high-Medicaid" facilities to request expansions at any time without being subject to the two-year limit, provided that the facility hasn't already submitted another request for exception that's pending with the agency.

2. Include Beds in POH Baseline

Current Rule: The limit on a particular POH's expansion is based on its "baseline," i.e., number of operating rooms, procedure rooms and beds for which it was licensed. State laws determine which beds count as being licensed.

Proposed Change: CMS proposes to revise the definition of "baseline number of operating rooms and beds" to clarify that "a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State." Translation: CMS will consider a bed to be "licensed" as long as it's within the hospital's State-approved "bed complement."

Takeaway

Compared to the value-based care package (see the item below), the "whole hospital" issue is just an hors d'oeuvre. Even so, the current limitations on POH expansion has been a bone of contention with physicians for nearly a decade. The newly proposed Stark changes, which are likely to be adopted, will offer a measure of relief give physicians greater leeway to expand POHs.

Healthcare Organizations Urge Fast Action on Value-Based Care Kickback Relief

Last October, after years of study and investigation, HHS, CMS and the OIG finally unveiled a package of regulatory changes designed to relax current Stark Law and Anti-Kickback Statue rules and facilitate value-based care arrangements. (See *National Intelligence Report*, Nov. 15, 2019). But the final rules are bogged down in the White House Office of Management and Budget (OMB) and it's unclear when they'll be released. On August 5, a group of 120 healthcare organizations, trade groups, suppliers and vendors issued a letter asking the President to take fast action and approve the proposed changes. "With the completion of this important work so close at hand, a single word from you would lift your team across the finish line," the letter urges.

Medicare Reimbursement: The 4 Things Labs Need to Know about CMS' Newly Proposed 2021 OPPS Rule

On August 4, CMS posted the proposed Outpatient Prospective Payment System (OPPS) Rule for 2021. In case you don't feel like reading all 785 pages of the Rule, here's a high level summary of the four notable changes that managers of labs providing services to hospital and ambulatory surgical center (ASC) outpatients need to know about.

1. 2021 OPPS Payment Rates

CMS is proposing a 2.6 percent increase to overall 2021 OPPS rates based on the following factors:

- Market basket update of +3 percent; minus
- The Affordable Care Act (ACA)-required multifactor productivity adjustment of -0.4 percent.

And, of course, hospitals failing to meet their Outpatient Quality Reporting ("OQR") requirements will continue to be subject to a 2 percent payments reduction.

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2. Changes to Laboratory Date of Service (DOS) Rules

CMS wants to exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analysis (MAAAs), which generally aren't performed in the hospital outpatient setting, from the Hospital OPPS packaging policy and add them to laboratory DOS provisions instead. Result: MAAAs would be reimbursed under the Clinical Laboratory Fee Schedule (CLFS) rather than the Hospital OPPS. Such tests would have to meet the DOS requirements with the testing lab directly billing Medicare for the tests.

3. Extension of Prior Authorization Requirements

To curb unnecessary utilization, last year CMS implemented a mandatory new process for hospitals to submit a prior authorization request affirming that an outpatient service is covered before delivering providing and billing Medicare for it. The requirement applied to five categories of services:

- Blepharoplasty;
- Botulinum toxin injections;
- Panniculectomy;
- Rhinoplasty; and
- Vein ablation.

CMS wants to add two new services to the prior authorization list for CY 2021: cervical fusion with disc removal and implanted spinal neurostimulators.

4. Elimination of the Inpatient Only (IPO) List

CMS has determined that medical and technological advances have eliminated the need for the IPO List of services requiring inpatient care due to the invasive nature of the procedure, the need for postoperative recovery time or the patient's underlying physical condition of the patient and is proposing to eliminate it over a three-year period, starting with the removal of 300 musculoskeletal services in 2021.

What's Not Changing: The Site-Neutral Payment Policy for Clinic Visits

For many labs, the biggest story of the proposed 2021 OPPS rules is what's not changing, namely, the controversial site-neutral policy for payment of clinic visits. **Explanation:** No service is more commonly billed under the OPPS than outpatient clinic visits for patient assessment and management. More often than not, these visits occur in a physician's office. In 2020, CMS cited its authority to restrict unnecessary increases in the volume of covered services, to complete implementation of a new rule to reimburse visits provided at an off-campus provider-based-department

(PBD) under OPPS at the Medicare Physician Fee Schedule (MPFS) rate for the clinic visit service (G0463 – Hospital outpatient clinic visit for assessment and management of a patient).

Hospitals claimed that CMS lacked the authority to implement the new policy. In September 2019, a federal district court agreed; but the hospitals' victory was short lived when in July, the U.S. Court of Appeals for the District of Columbia Circuit reversed the lower court and ruled in CMS' favor. Bottom Line: The site-neutral policy will continue in 2021. Moreover, the agency is considering going back and reprocessing 2019 claims that were previously reprocessed at the higher OPPS rate.

See the story on **page 7** about the Stark Law changes the Rule proposes.

Takeaway: Brace Yourself for a Quick Turnaround

The deadline to comment on the proposed Rule is October 5. As per usual, CMS is expected to publish the Final Rule some time in early December. Normally, changes to the Final Rule take effect 60 days after finalization. However, due to the public health emergency, this year CMS plans to implement the Final Rule in 30 days, leaving outpatient testing labs little time to adjust to the changes.

DOJ Watch: Federal Appeals Court Tosses Cold Water on DOJ's Crackdown on Weak Whistleblower Suits

It's fair to say that when it comes to False Claims Act (FCA) whistleblower *qui tam* lawsuits, the current U.S. Department of Justice (DOJ) is less enthusiastic than its predecessor. In fact, the DOJ has pursued a policy of actually seeking to dismiss *qui tam* claims it deems weak or not in the public interest. On August 4, that policy came under challenge in the federal appeals court for the Ninth Circuit.

Spoiler alert: The court denied the government's motion to dismiss a *qui tam* suit. Here's a rundown and an explanation of how all of this may affect you.

Granston Memo, 101

Under the FCA, whistleblowers (aka "relators") suing companies for ripping off the federal government must be filed under seal to give the DOJ time to decide whether to intervene. Relators can still go forward with the case; but if the DOJ declines their leverage decreases and risks increase.

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DOJ Watch: Federal Appeals Court Tosses Cold Water on DOJ's Crackdown on Weak Whistleblower Suits, *from page 11*

The government can do more than simply decline to intervene in the case. The FCA (Section 3170(c)(2)(A)) allows it to actually seek to have the case dismissed if it thinks the suit doesn't serve its interests. Historically, though, the DOJ rarely seeks dismissal under Section 3170(c)(2)(A).

But that all changed in January 2018, when DOJ Civil Fraud Section Director **Michael Granston** issued an internal memorandum instructing U.S. Attorneys to be more aggressive in exercising their Section 3170(c)(2)(A) powers, which the Memo describes as crucial in enabling the agency to perform its "gatekeeper role" in preserving enforcement resources, protecting government interests and preventing weak cases from resulting in adverse judgments that weaken government enforcement powers. The Memo goes on to outline seven kinds of problematic *qui tam* claims that U.S. Attorneys should target for dismissal. (For more details, see *National Intelligence Report*, March 19, 2018.)

The Ninth Circuit Case

Sure enough, U.S. Attorneys have been following their marching orders and seeking dismissals of *qui tam* cases under Section 3170(c)(2)(A). Even though it's not a healthcare case, the Ninth Circuit ruling is significant because it's among the first to test the limits of the Granston Memo policy. The case reached the Ninth Circuit after the lower court denied the government's motion to dismiss the *qui tam* of a relator accusing a mortgage lender of submitting false claims to the Federal Housing Administration (FHA). Denial was unwarranted, the Northern District of California court held, because the government failed to:

- Demonstrate a valid governmental purpose for dismissal; and
- Fully investigate the allegations of the complaint.

The government appealed the ruling on technical jurisdictional grounds, but the Ninth Circuit wouldn't budge. (*United States v. United States ex rel. Thrower*, No. 18-16408 (9th Cir. 2020).

Takeaway: Getting *Qui Tam* Cases Dismissed May Not Be So Easy

For better or for worse, the Thrower case represents a setback to the Granston Memo policy to the extent it indicates that courts may not be so willing to give the government unfettered discretion to get qui tam cases tossed out under Section 3170(c)(2)(A). The really troubling part for prosecutors is the "fully investigate" requirement, which imposes a new and potentially costly administrative burden on enforcement resources, precisely what the Granston Memo "gatekeeping" mandate seeks to avoid.

What makes the "fully investigate" pill even harder for the DOJ to swallow is how the case actually unfolded. At first, the DOJ just declined

to intervene. The decision to seek dismissal came later after the relator amended her claim. In other words, the claim the DOJ wanted tossed out of the court wasn't the same claim it reviewed in declining to intervene. So, now it would have to do a new investigation. The concern is that relators with lousy or harmful cases will be able to tie the DOJ in knots and evade Section 3170(c)(2)(A) dismissal simply by amending their claims.

But while this is the first challenge to the Granston Memo policy, the Thrower case will definitely not be the last. So, stay tuned for further developments.

2021 Medicare Physician Fee Schedule: Slashes Lab Reimbursements 5% but Provides Some PAMA Relief,

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5 percent, and to pathologists by roughly 9 percent, according to CMS' projections. By contrast, the 2020 PFS increased overall lab payments by 1 percent payments for pathology even with 2019 levels. Among the largest scheduled cuts is to the professional component of pathology tissue examinations, which is slated to drop 12 percent to $34.52 to $39.34.

3. One-Year Delay in PAMA Reporting

The news isn't all bad. Delivering on promises made during the March CARES Act COVID-19 relief bill negotiations, the next round of PAMA Clinical Laboratory Fee Schedule (CLFS) data reporting period would be delayed by an additional year. **Result:** Hospital outreach labs won't need to report private payor data until Jan. 1, 2022 through March 31, 2022.

4. PAMA Pricing Relief

CMS is proposing phased-in CLFS payment reductions through 2024 by imposing a 0.0 percent reduction for CY 2021 and a 15 percent reduction cap for the next three years after that.