Volume XXV, Number 16 Tuesday, November 13, 2018

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

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Founder & Publisher

More Medicare Price Cuts Coming in 2019, 2020

How many consecutive 10% and 15% cuts to the prices Medicare pays for clinical laboratory tests can smaller community labs absorb before they are forced to shut their doors and go out of business? This nation is about to find out. As this happens, Medicare beneficiaries (and their physicians) in small towns and rural areas will lose access to the quality lab testing services they have relied on for decades.

The first round of 10% price cuts to the Medicare Part B Clinical Laboratory Fee Schedule took place on Jan. 1 of this year. In the 11 months since those lower prices took effect, several clinical lab companies closed their doors and went out of business.

The **National Independent Laboratory Association** (NILA) says that its members are experiencing significant financial erosion as a result of this year's 10% fee cuts. When the 10% fee cuts for 2019 and 2020 are implemented (representing a collective 30% price cut from Medicare Part B lab test prices in 2017), NILA predicts that the reduced revenue from Medicare for the same volume of Medicare patients will push many of these community labs into financial collapse.

Because the nation will lose these community labs one at a time, in different regions at different times, no one in the media is likely to notice. Nor will there be a groundswell of unhappy Medicare beneficiaries contacting their senators and representatives to complain about losing the reliable lab provider they have used in their town or region for decades.

Within the clinical lab industry, the largest lab companies will manage to absorb the Medicare fee cuts. They will survive even as smaller clinical labs disappear. But what will be gone are the local laboratories that have faithfully served their small towns and rural areas.

Who will provide this testing when these labs go out of business? Physicians and nursing homes in these communities are the same ones abandoned by the public lab companies in the 1990s when they determined these clients were unprofitable. History tells us that today's national lab companies won't fill that void because of the high costs of serving providers in those communities. Thus, as CMS moves ahead with its plan to enact deep price cuts uniformly across all labs and all regions, it is Medicare beneficiaries who will suffer because they will lose access to quality lab testing provided locally. TDR

NILA, ACLA Respond to CMS 2019 Final Lab Rule

Adjustments in data collection processes won't start for two years, thus deep cuts start on Jan. 1

CEO SUMMARY: On Nov. 2, the federal Centers for Medicare and Medicaid Services released its Physician Fee Schedule for 2019. It says it will expand the number of labs from which it collects data about the lab test prices paid by private health insurers. While some labs may welcome these changes, groups representing clinical laboratories said the changes CMS calls for won't take effect for two years. Meanwhile, on Jan. 1, CMS will make another 10% cut in what it pays for lab tests under the Protecting Access to Medicare Act.

THERE IS BAD FINANCIAL NEWS for clinical laboratories following the publication on Nov. 2 by the federal **Centers for Medicare and Medicaid Services** (CMS) of the final rule for the 2019 Medicare Physician Fee Schedule.

Sections in the final rule specify improvements in the way CMS will collect data on the prices private health insurers pay clinical labs. While some labs may welcome these changes, groups representing clinical laboratories noticed a significant flaw in the plan, said Mark S. Birenbaum, PhD, Administrator of the **National Independent Laboratory Association** (NILA) and the **American Association of Bioanalysts**.

"Included in the new physician rates for 2019 were corrections to problems that have plagued the clinical lab industry since Congress passed the Protecting Access to Medicare Act (PAMA) in 2014," explained Birenbaum. "However, those corrections will not take effect for two years. Therefore, just as the Medicare Part B Clinical Laboratory Fees were cut by 10% at the start of 2018, comparable price cuts will be enacted in each of the next two years."

Medicare prices for many clinical lab tests will be cut a collective total of 30% during the years 2018, 2019, and 2020. These price cuts are the result of the market study conducted by CMS and how it used that data to set prices as directed by the language of the PAMA law. The clinical laboratory industry has complained that CMS used a flawed data-collection process to produce the deep fee cuts that will happen during these three years.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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In the final rule for the 2019 Medicare Physician Fee Schedule, CMS said it will adjust the methods it uses:

a) to collect private health insurer price data from labs serving Medicare Advantage members; and,

b) to use the CMS-1450 14x claims form to categorize hospital outreach laboratories as being applicable laboratories under PAMA.

"Theoretically, these changes will increase the number of hospital outreach laboratories required to report applicable data," noted Birenbaum. "CMS expects this change to capture private payer price data from a larger portion of the laboratory market."

Julie Khani, President of the **American Clinical Laboratory Association** (ACLA), had a similar comment about the language in the 2019 Medicare Physician Fee Schedule (MPFS), saying, "it recognizes the flaws in the agency's approach to implementing PAMA and represents a starting point in advancing a more sustainable, competitive market for millions of seniors who depend on clinical diagnostics for their health."

Intent of Congress

Khani qualified this statement by noting that "CMS has not implemented PAMA as Congress intended, requiring action from Congress to ensure that labs and patients are not harmed further." ACLA also is pursuing a lawsuit against **Health and Human Services'** Secretary Alex M. Azar for unlawfully instituting a flawed data collection process in the transition to a market-based payment system, Khani added.

Birenbaum said the problem with the language of the 2019 MPFS is that the changes CMS says it will make won't take effect until at least 2021. "In other words, the fees for 2019 and 2020 aren't affected by what CMS says it will change in this Medicare physician fee schedule," he stated. "It means labs may not see any improvement from these changes until CMS does its next data collection and uses that information to set medical lab test prices for the next three-year cycle—2021 through 2023."

For clinical labs, the three-year cycle creates two problems, both of which have a negative effect on what CMS pays for clinical lab tests.

Financial Survival

"The first problem is labs must financially survive through 2019 and 2020 and, in each of those years, CMS is scheduled to cut what it pays labs for most lab billing codes by 10% each year," stated Birenbaum. "Throughout this year, medical labs have struggled under a price cut of 10% that went into effect on Jan. 1.

"The second problem is that we don't know how much these changes will affect the data CMS collects as to the prices labs are paid by private health insurers in coming years," he added. "It's not clear how much additional marketplace data CMS will include when they make these changes. Compared to the first data collection effort, we know now that CMS will collect data from more labs, but we don't know the specifics about which labs are to be included and which are to be left out."

As THE DARK REPORT has reported, some clinical labs have reduced services and others have gone out of business, particularly community laboratories serving nursing homes and long-term care facilities located in rural areas.

Next Round of Lab Fee Cuts

Birenbaum noted that, while CMS appears to be making an effort to fix some problems with how it collects data in private payer prices for lab tests, Medicare officials will once again move forward to institute lower rates beginning in January. This means labs "face a second unsustainable 10% price cut in less than two months," Birenbaum said.

"This imminent price cut threatens Medicare beneficiaries' access to crit-

Final 2019 Medicare Physician Fee Schedule Has Significant Changes for Clinical Labs

RELEASE OF THE FINAL RULE for the 2019 Medicare Physician Fee Schedule (MPFS) gave the clinical laboratory industry an opportunity to see how officials at the Centers for Medicare and Medicaid Services (CMS) responded to the large number of public comments it received following its publication of the 2019 MPFS proposed rule last July.

CMS put the 2019 MPFS on display at the Office of the Federal Register on Nov. 1. The final rule is scheduled to be published in the *Federal Register* on Nov. 23.

For the clinical laboratory industry, the most significant change in the 2019 MPFS is that CMS expanded the definition it uses for "applicable laboratories." Those hospital outreach laboratories that receive payments from the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) totaling at least $12,500 from claims submitted on the CMS-1450 14x bill type will now be "applicable laboratories" and must report the lab test prices they are paid by private health insurers.

The next reporting period, which CMS will use to set prices for the second three-year period (2021-2023), comes in 2019. Applicable laboratories will need to report this data for payments made during the period Jan. 1, 2019, through June 30, 2019.

The data to be reported must include the HCPCS/CPT code for each test, the rate paid by every private payer for each test (after all discounts and contractual adjustments), and the volume of each type of test that corresponds to that payer's rate.

Another change in the final rule is that CMS revised its definition of an "applicable laboratory" to exclude Part C Medicare Advantage payments in certain calculations. CMS believes this will increase the number of laboratories reporting private payer prices.

Clinical labs throughout the United States won't have much time to respond to the changes CMS enacted in the final 2019 Medicare Physician Fee Schedule. The reporting period starts on Jan. 1, 2019.

One section of the PAMA statute sets out penalties for clinical laboratories that fail to report, or report incomplete data, or inaccurate data on the prices they were paid by private health insurers. In the first cycle of data gathering, federal officials did not assess penalties against any clinical laboratory. Will this be true during the next cycle of data-gathering? CMS has made no statement about how it may penalize labs now or in the future.

ical laboratory services because—after this next price cut takes effect—the drop in revenue will make it difficult or impossible for many commmunity laboratories to sustain their testing services for Part B Medicare beneficiaries," he emphasized.

30% Cut to Medicare Fees

"Smaller community labs operate on profit margins between 5% and 10%," noted Birenbaum. "These labs may not survive a 30% cut in Medicare fees. This is especially true of those labs serving nursing homes, for example, where the bulk of their income is from serving Medicare beneficiaries."

When labs struggle financially, the first step they take is to reduce services. "This year, we've seen a number of labs cut back services to physicians and patients because of the deep reductions to Medicare test fees," he said. "With this next round of price cuts soon to take effect on Jan. 1,

2019, we will see community labs merge or be acquired because owners cannot financially sustain their lab operations. We will also see some labs simply close their doors and walk away. Some labs did that this year.

"Labs that struggle might be able to survive for one year, but following additional 10% cuts in year two and year three more labs may be unable to survive," Birenbaum added.

Will Congress Act?

"Congress could address this situation," he added. "NILA, with others, started a grassroots campaign to persuade members of Congress to pass a moratorium on making further cuts under PAMA. We encourage labs to join NILA on this effort.

"During the lame-duck session of Congress that is starting now, the lab associations will engage with members of Congress to get something done before Jan. 1," he added.

In conclusion, Birenbaum said, NILA continues to oppose how CMS implemented PAMA. NILA says CMS should set lab test rates based on the entire clinical laboratory market, and to delay future cuts under Medicare Part B until a complete market study is performed.

With issuance of the 2019 MPFS final rule, clinical laboratories now understand what changes CMS officials will make to how it conducts the second market study of the prices private health insurers pay for laboratory tests. However, these changes do not address or correct the problems and flaws that have been regularly identified and described by lab professionals, their attorneys, and other lab industry experts. That leaves action by Congress or success in federal court as ways the clinical lab industry could fix these problems. TDR

—Joseph Burns

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Hospital Labs Face Challenge to Report Payer Lab Prices

MANY IN THE CLINICAL LAB INDUSTRY would consider it a positive development that the Centers for Medicare and Medicaid Services will require an expanded number of hospital outreach laboratories to report the lab test prices they are paid by private health insurers during the next reporting cycle.

But adding the price data from hospital outreach laboratories presents its own challenges for those organizations.

It is widely-acknowleged that most hospital laboratories have disparate software systems which are designed for a different era of healthcare, lab test ordering/reporting, and laboratory billing/coding/collections.

Following the Nov. 1 release of the final rule, lab industry consultants and experts have spoken out about the difficulties that hospital outreach labs will have to provide accurate and complete price data from private payers. This will be similarly true for many community lab companies that serve nursing homes and long-term care facilities.

Labs must report accurate and complete data in a timely manner to CMS. Failure to do so can subject the lab to substantial penalties, defined in the Protecting Access to Medicare Act as up to $10,000 per day for a laboratory that fails to report, or has misrepresentations or omissions in the data it submits to CMS.

For labs required to report this data, lab billing consultants advise keeping source documents, logs, and other information to support how they gathered their private payer price data.

It may be a positive development for the clinical lab industry that more hospital outreach labs are now applicable labs for PAMA private payer price data reporting. But such reporting creates new risks for those same hospital labs.

Project Santa Fe Labs Deliver Value with Tests

Member labs are innovating in ways that add value to lab services and improve patient care

CEO SUMMARY: No bigger threat looms over the financial security of the nation's clinical laboratories than healthcare's transition from fee-for-service payment to value-based reimbursement. To navigate that transition successfully, medical labs and pathology groups will need to adopt the Clinical Lab 2.0 model. Member labs of Project Santa Fe are themselves working to develop and implement lab services that add value and for which health insurers will want to reimburse.

PROJECT SANTA FE IS ON THE MOVE. In recent months, the four participating medical lab organizations incorporated a foundation and selected an executive director for that foundation. Last week it conducted its second annual national conference on value-added lab testing services in Chicago.

Founded in 2015, **Project Santa Fe** is a collaboration of the clinical laboratory organizations of four prominent health networks. The primary goal is to develop value-added lab services and demonstrate the improvement in patient outcomes and reductions in the overall cost of care. Although health insurers are not yet paying for these services, they have expressed an interest in doing so. *(See sidebar on page 9.)*

Replicating Lab's Success

Next, as one lab's value-added program delivers clinical improvements, the Project Santa Fe lab members intend to replicate those same value-added programs in their own institutions. The four institutions will publish the results of these programs in peer-reviewed healthcare journals to educate health policy-makers and payers about how these programs and laboratory professionals can contribute to improved patient outcomes and lower costs of care. *(See TDRs, Jan. 30, May 15, and June 5, 2017.)*

The four Project Santa Fe laboratory organizations are:

- **Henry Ford Health**, Detroit;
- **Geisinger Health**, Danville, Pa.;
- **Northwell Health**, Lake Success, N.Y.;
- **TriCore Reference Laboratories**, Albuquerque, N.M.

The four chairs of pathology of these laboratory divisions incorporated the **Project Santa Fe Foundation, Inc.** (PSFF) and are working to register it as a 501(c)3 not-for-profit company.

The new Executive Director of PSFF is Khosrow R. Shotorbani, MBA, MT (ASCP), the former CEO of Tricore Reference Laboratories. Shotorbani is the founder and CEO of **Lab 2.0 Strategic Services**, a consulting firm in Salt Lake City.

The project's second annual *Clinical Lab 2.0 Workshop* attracted 115 attendees. They represented hospital and independent lab professionals, along with professionals from *in vitro* diagnostics (IVD) and lab software companies.

At its core, Project Santa Fe aims to guide labs in their efforts to stay ahead of the transition away from fee-for-service reimbursement and to payment for value. "For clinical labs, the danger of not shifting along with health systems as they move to pay for value is that labs could be left behind," stated Shotorbani. "Under that scenario, labs would be responsible for little more than delivering test results as a commodity.

"Labs that do not work closely with their parent health systems and insurers to deliver value will be left collecting payment based on volume only," he added.

To describe this new model for lab services that add value, Project Santa Fe has developed the concept of Clinical Lab 2.0. "Labs ready to make this transition need to think in three strategic ways," advised Shotorbani.

"First, pathologists and lab managers need to set a value for the longitudinal data they have from producing clinical lab test results on patients over many years," he noted. "These data are stored in patients' electronic health records, data warehouses, or other secure locations.

Payments with Financial Risk

"Second, clinical labs need to use that longitudinal data to support the delivery of value-based care to health systems operating under models of payment in which they have assumed financial risk," he said.

"Health systems operating as accountable care organizations (ACOs) in which they get paid under shared-savings arrangements for caring for Medicare patients are one example," he continued. "Health systems running bundled payment and patient-centered medical homes are two other examples.

"Third, to facilitate this shift, clinical labs need to negotiate new forms of payment from health systems and health insurers that reward the work of labs delivering data to support value-based care," he stated. "To do so, clinical labs will need to move away from what we call the Lab 1.0 model. Under Lab 1.0, insurers and health systems pay for volume and often fail to recognize the value clinical labs can deliver in improving patient care.

"By contrast, the lab operating as the Clinical Lab 2.0 model has the mission of working with integrated health networks and health insurers to support physicians in keeping patients well and helping them manage patients with chronic conditions in a proactive manner," explained Shotorbani. "To do that effectively, a clinical lab needs to do three things: intervention, prevention, and cost avoidance."

New Ways to Help Patients

As Executive Director of the Project Santa Fe Foundation, Shotorbani will showcase the work of its clinical lab and health system members who are developing new ways to deliver value to physicians, payers, and patients, he said.

"One goal at Project Santa Fe is to change the conversation among health systems and payers and clinical labs," noted Shotorbani. "Changing the conversation is a critical factor for clinical labs now because, under the Protecting Access to Medicare Act of 2014, payment from Medicare to labs has been slashed and is scheduled to continue to decline.

"If we do nothing, then clinical labs will continue to head toward what I call the commoditization of lab results," he commented. "No one in the lab industry wants that. But if we don't change the conversation, that will happen.

"Clinical labs still organized around the volume mindset will not survive under new payment models," he predicted. "That's why I view the foundation's role as spreading the word about how labs can deliver value to health systems and payers."

Last year, the *Journal of Applied Laboratory Medicine* (*JALM*) published an article by researchers from TriCore Reference Laboratories. Before starting

his consulting practice, Shotorbani led Tricore's efforts to demonstrate how physicians can use lab data to improve patients' outcomes and lower costs using clinical lab results strategically.

In the *JALM* article, the researchers explained that TriCore and other labs can "provide meaningful clinical diagnostic insights for population health initiatives that result in improved short- and long-term patient outcomes while supporting cost-effective care."

Labs can do so by analyzing patients' longitudinal laboratory data over many years, identifying targeted interventions for specific patients, and developing clinical decision support tools, wrote Kathleen Swanson and colleagues. Swanson is TriCore's Director, Enterprise Clinical Solutions. Three clinical conditions stood out as being potentially appropriate for value-based care based on the use of longitudinal lab test results, the researchers explained. Those conditions are diabetes, acute kidney injury that can lead to costly chronic kidney disease, and premature births.

For patients with pre-diabetes, a lab could identify and track these patients to avoid disease progression, a method that would be less costly than waiting for these patients to develop uncontrolled diabetes, which costs health systems an average of $10,500 per patient per year.

For a project designed to prevent premature births, TriCore identified lab tests and screening methods needed to monitor pregnant women and create a work list that was integrated into the health plan's daily workflow for care coordinators. "Value for the demonstration project was measured using premature births, hospital costs, reimbursement for prenatal and postpartum quality measures, and ER visits," wrote the researchers. As of last year, the three projects and associated data collection were still ongoing in New Mexico. TDR

—Joseph Burns

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Insurers Use Lab Data for Clinical Insights

WHEN CLINICAL LABORATORIES PURSUE new ways of contracting, they want to know how health insurers will respond. The goal is to find ways that laboratories can be paid for contributing value to clinical care.

In recent years, TriCore Reference Laboratories of Albuquerque, N.M., developed new informatics solutions that use lab data and other clinical information to show how the lab can best serve health systems and payers delivering care under value-based payment arrangements.

To date, health insurers have not yet started paying for this work, but they are beginning to use lab test data for clinical insights, said Michael J. Crossey, MD, PhD, TriCore's CEO and Chief Medical Officer. Among some insurers, there is interest to pay labs such as TriCore that are on the leading edge of the Clinical Lab 2.0 movement, he added.

"Tricore has a contract in which it's paid on a per-member-per-month basis to provide clinical insights, and that PMPM contract is outside of the lab services contract we have with that insurer," he commented. "This contract might be the first of its kind for a lab.

"In addition, we have several prospective contracts under review with other insurers that we work with here in New Mexico," he added. "What we're learning is that lab data is not necessarily a magic bullet to control healthcare costs.

"That's because somebody on the clinical delivery side of care has to deal with those patients who are revealed through lab work as needing some form of intervention," explained Crossey. "Using lab data to put up a red flag isn't going to bend the outcomes and cost curves. There has to be a system in place to initiate further action by clinicians."

Lab is paid for value of its actionable intelligence

Sonic Uses Lab Data, Patient-Contact Tools, to Improve Outcomes

CEO SUMMARY: In its work for a federally qualified health center, Sonic Healthcare USA helped physicians use a data-driven approach to population health management that incorporated integrated financial and clinical analytics. Also, Sonic developed technologies that give ordering physicians clinical decision support and targeted patient engagement tools. It then developed a way to contact patients who had gaps in care. From its work with this health center, Sonic was asked to be more than a lab provider.

With the era of fee-for-service payment soon to end, all clinical labs face a common question: If labs will not be paid a per-test fee, how will they generate adequate revenue to sustain lab testing operations?

Nothing less than financial survival is at stake. If payers consider lab testing to be a commodity, then only clinical labs with the lowest costs will survive, but they will do so only by accepting the lowest rates.

Stated differently, the labs that thrive will do more than just report accurate lab test results for the lowest fee. Rather, they will provide diagnostic services that contribute to improving patient care in measurable ways.

For this group of labs, payers will measure value in two ways. First, they will want diagnostic services that help physicians document improvements in patient care. Second, diagnostic services will help reduce the cost of care for each individual encounter or the entire episode of care or both.

The good news for hospital and independent laboratories that go down this path is that health plans and physicians are willing to pay them for this increased value, particularly in the form of sizable shared savings payments.

Such is the case in Texas and New York with innovative collaborations that **Clinical Pathology Laboratories** (CPL) and **Sunrise Medical Laboratories**, divisions of **Sonic Healthcare USA**, have implemented. In recent years, a large multi-physician group operating as a federally qualified health center (FQHC) engaged Sunrise Medical Laboratories to help it use lab test data to improve patient outcomes and reduce the cost of care for patients with diabetes and chronic kidney disease (CKD).

Sunrise used Sonic's iMorpheus, its informatics system, to provide data to manage the patients and help close gaps in care for the FQHC, accountable care organizations, physicians groups, and other integrated delivery networks. For these services, Sonic Healthcare negotiated reimbursement in the form of outcomes- and value-based contracts and shared savings arrangements.

In September, Philip C. Chen, MD, PhD, Chief Healthcare Informatics Officer for Sonic Healthcare USA, gave a presentation on this topic at THE DARK REPORT's *Precision Medicine for Health Network CEOs* conference in Nashville. Chen described how community-based physicians struggle to adopt new technology for clinical lab testing.

"We can do all the sophisticated lab testing we want, but it's still very difficult to get community-based physicians to actually use these services," he commented. "It's difficult unless these physicians can see the value of such services in terms of improved patient care and the ability to use such services to develop value-based payment."

Data-Driven Approach

In a case study for the FQHC, Chen outlined how Sonic helps physicians use a data-driven approach to population health management. "Sonic uses integrated financial and clinical analytics and deploys technologies that give ordering physicians clinical decision support and targeted patient engagement tools," stated Chen.

"Our goal is to go beyond simply being a provider of timely and accurate clinical lab test results," he added. "One way we learned to deliver more value to ordering physicians was to develop tools to contact patients who had gaps in care."

Chen explained that once Sonic deployed the patient-contact tools it developed for the FQHC, other payers, including an accountable care organization (ACO), became interested in the cost savings potential of identifying patients with chronic conditions and using Sonic's patient-contact tools.

"The full set of tools Sonic provided enables physicians to develop contracting strategies that helps them and Sonic

get paid in settings beyond fee-for-service," Chen said. "The FQHC physicians using Sonic's informatics systems were using data to support value- and outcomes-based contracting and to collect shared savings from payers.

50% of Spending

"In our work with organized delivery networks, such as accountable care organizations and integrated provider networks like they have in California, we saw that health plans were spending very little money for most patients," Chen explained. Nationwide, about 5% of patients account for 50% of all spending.

"In our work with one California health plan, we analyzed the claims status of their 75,000 patients and tracked patient expenditures from one year to the next," he said. "For this health plan, we showed the health plan that it was spending very little money on a very large percentage—88%—of its members. But for 1% of its members, the health plan was spending an average of $61,000 per patient per year!

"What's striking about following these patients from one year to the next is that some patients move from being low-expenditure patients to being high-cost patients," Chen commented. "About 62% of high cost patients in one year (2014) were costing the health plan very little in healthcare spending in the previous year.

"At Sonic, we wanted to know if we could identify those patients before they started costing a lot of money," he added. "To answer that question, we had to know why they suddenly started costing a lot of money. Then—as a lab provider—could we identify an opportunity to stop them from moving into the high-cost category?

"By analyzing the diagnosis codes for that high-cost group, we could list the most expensive patients per capita," Chen explained. "Those patients fell into 16 disease conditions.

"For this analysis, we removed those patients who had a one-time event that is not preventable through healthcare management, such as a car accident or hip replacement," he noted. "That left those patients who had one or more of the 16 chronic diseases for which physicians can intervene."

Ranked in order starting with the most costly, those 16 chronic conditions are:

- Renal failure*
- Chronic liver disease
- Congestive heart failure (CHF)*
- Chronic obstructive pulmonary disease (COPD)
- Ischemic heart disease*
- Depression
- Asthma
- Diabetes*
- Hyperlipidemia*
- Hypertension*
- Rheumatoid arthritis
- Low back pain
- Morbid obesity*
- Osteoporosis
- Alcohol/substance abuse
- Mental/behavioral health

**Conditions that are comorbid with other conditions.*

Stratifying Patient Population

"Initially we looked closely only at diabetes and chronic kidney failure patients in both the Medicare and commercial claims population," commented Chen. "For both conditions, we identified a very small number of people who had extremely high expenditures.

"In 2008, data from the United States Renal Data System showed that—for a set of 27-million patients in the general Medicare population—the median age was 75.6 years," noted Chen. "Within this sample, CKD patients accounted for 8.7% of patients but 24.5% of costs and $49.7 billion in spending.

"In this same set of patients, congestive heart failure (CHF) patients represented 13.5% of the population but

Sonic Healthcare Adds Value by Using Lab Data in Combination with Tools

WITHIN THE TYPICAL LARGE PRIMARY CARE PRACTICE, there are often gaps in care that can be identified by the clinical laboratory provider. This was the opportunity that Sonic Healthcare used to become a clinical collaborator with certain physician clinics in New York and Texas. Chronic diseases like diabetes were the focus of this effort.

Baseline statistics for diabetes among primary care practice

15-20%

Patients identified by laboratory criteria who do not carry a diabetes diagnosis code.

20-35%

Patients who have not been seen for more than 12 months.

30-65%

Patients who have care gaps based on current guidelines and are due for follow up.

From its work with different primary care groups, Sonic Healthcare has learned the proportions of diabetic patients that typically don't have a diabetes diagnosis code, have not been seen in more than 12 months, and have care gaps, as shown above.

Responses from automated patient engagement and pre-visit lab services

44%

Patients who returned to clinic and had care gaps fulfilled by labs (of those returned, nearly half returned to the lab within 24 hours).

35-45%

Patients who did not return to clinic, mostly due to engagement issues (wrong phone number, moved away, no longer a patient of the practice, did not answer call, etc.).

7%

Patients who chose to opt out of the automated engagement service.

Based on physicians' use of Sonic's identification of patients who would benefit from getting care and its patient-contact tool, Sonic was able to encourage 44% of patients contacted to see their provider, thus helping to close those care gaps.

35.8% of spending, or $72.6 billion," he commented. "It was a similar story for diabetes patients who made up 23.6% of the population but represented 36.1% of Medicare spending, or $73.2 billion."

Chen then described the incidence and costs of these same diseases for a three-million member sample of the commercial population, where the median age is 56.6 years, as follows:

- CKD patients represented 1.3% of the population and spending for these patients reached 7.8% of total spending, or $1.2 billion.
- CHF patients were 1.3% of population and spending for these patients reached 7.8% of total spending, or $1.2 billion.
- Diabetes affected 10.6% of the commercial population and spending totaled 21.5% of total spending or $3.4 billion."

Opportunities for Labs

"These statistics demonstrate how much opportunity exists for clinical labs to deliver value that improves patient care and reduces healthcare costs," noted Chen. "Improving the management of just these three diseases can have a profound impact on outcomes and the cost of care.

"Another client relationship involved a large primary care group caring for about 50,000 patients," he continued. "Our analysis in iMorpheus produced interesting results. Along with our review of diagnosis codes we also reviewed the lab data for these patients.

"In this group, we identified a typical pattern that we see in primary care," he observed. "Among 3,700 diabetes patients, almost 700 of them did not have a diagnosis code assigned.

"Why was the diagnosis code missing for these patients?" asked Chen. "Did the doctors forget to add the code after treating these patients? The answers were interesting and represented our lab's opportunity to add value.

"For this group of physicians, we found that 27% of its patients had not seen a doctor in over 12 months," stated Chen. "We also found that, from one practice to another, there is a range of about 20% to 35% of diabetes patients who have not seen a doctor for over 12 months.

Patients with No Claims

"For these patients, there are no claims, meaning they are actually the low spenders in the claims analysis, but they have the disease," Chen said. "If they don't show up for care, how do they get diagnosed?

"What frequently happens is that these patients see a doctor who suspects there is a problem and orders a lab test," he explained. "But these patients are asymptomatic and so they don't come back. That means there is no clinical encounter for the physicians to record the diagnosis in the EMR, even though their screening lab test results showed they have a problem. With no identifying code, they do not get followed or treated.

"But these patients are still sitting out there and the physician groups are responsible for the costs of their care," noted Chen. "Over time, of course, those people with diabetes develop complications and they show up in the hospital. That's when they jump from being low-cost to high-cost patients.

Diabetes Under Control

"On the other side, when we reviewed the data on those patients with diabetes who do show up regularly for routine physician care, we saw a significant number of them controlled their diabetes fairly well," he added. "This observation challenges the premise that clinical decision support tools are effective to remind doctors about what they need to do. That premise may be incorrect. The key issue is not with the doctors, but with patients who do not show up for routine care.

"How do we address this failure-to-show-up problem?" asked Chen. "At Sonic,

our answer was to create scorecards and a gaps-in-care roster that lists each physician's patients with a chronic disease who are overdue for routine lab monitoring."

In this way, Sonic is moving beyond simply reporting timely, accurate lab test results and is developing tools to help physicians improve patient care.

"The scorecard is useful because most physicians don't know how many diabetes patients they have, much less who are overdue based on standard clinical guidelines," continued Chen. "This scorecard and other tools we give them is a first step that allows them to identify those patients. But it doesn't solve the problem if the patients don't show up.

CASE STUDY: FQHC

"When we started this program about four years ago, our first client was a large federally qualified health center in New York with about 100,000 patients," Chen said. "We analyzed their lab data and then sent the FQHC a list of 1,200 patients' names who needed follow-up care. We said, 'You need to call these patients because they need to be brought back for a follow-up visit with a physician.

"The chief operating officer of the center looked at me and asked, 'Why do you expect me to call these patients back? Since you found them, why don't you bring them back? I'm not looking for a laboratory; I'm looking for a healthcare partner.'

"That response was unexpected and it triggered an interesting discussion about the role of the laboratory in managing patient care," Chen explained. "From that point, we expanded our ways to help.

"As a clinical lab, we don't have the personnel to call patients back," he said. "Therefore, we developed technologies that we can deploy—automated calls, voicemail, e-mail, and text messages—to alert patients that they are due for follow-up visits with their physicians.

"Our lab deploys these methods on behalf of the physicians," he stated. "A first step is to record the physician's voice. That way, patients hear their own doctors calling them to say they need to come back for an office visit.

"Here's how our patient contact program works," he added. "Each week we send an e-mail to the physician with their patient data. It shows them which patients need follow-up, based on diagnosis codes, prior lab results, and evidence-based care guidelines.

"This informs the physician about how many and which patients are overdue for the needed tests in accordance to the current clinical guidelines," Chen continued. "The physician and the clinic staff can then check to see if those names on the list are still active patients.

"If a patient has moved away and is no longer active, the physician can opt the patient out," he said. "Our service gives the physicians a three-click strategy. With one click they will authorize the patient list and select the outstanding laboratory tests for standardized routine care. With a second click, they authorize the ICD codes, and the third click authorizes the lab orders.

Patients Are Contacted

"When they authorize the lab orders, two things happen," noted Chen. "First, the orders get sent to our patient service centers so that our PSCs can prepare to test these patients when they show up. Second, all the calls, e-mails, or texts go out to the patient.

"If the patient answers the call, we ask them if they're ready to make an appointment," he commented. "If yes, we transfer the patient to their provider to schedule a visit. Before we transfer the call, we tell the patients their doctor has ordered lab tests for them and so they should visit the lab before seeing the doctor.

"That process saves the patient an office visit," Chen explained. "Usually when a patient sees a doctor, the patient will get a lab order and then go to the lab. But then the patient needs to see the doctor again a second time a week or two

weeks later for follow-up management. With our system, the patient gets the lab test done before seeing the doctor, so that everything is done in just one visit with their physician.

"In addition to sending physicians a list of patients who need follow-up visits, we also stratify the list by putting the most critical patients on top," he added. "Our algorithm is based on clinical laboratory data, which allows us to show how severe that patient's disease markers are and how long it's been since the patient's last physician visit."

Stratification System

"Our service includes an integrated stratification system that uses diagnosis codes to help us predict the likelihood of a high-risk event that could cost a lot of money or an event that might require an inpatient admission to the hospital," he explained. "This stratification integrates **Johns Hopkins** ACG algorithms to identify those patients most likely to experience complications and high-expenditure events.

"We are not making a prediction. Rather, our tool is useful to prioritize the list," added Chen. "Because all these patients need to come back, we put the most needy patients on top.

"In the first 39 primary care practices, we had data on about 200,000 patients and used this technology to follow them for more than six months," stated Chen. "Among those 200,000 patients, there were about 14,000 who had diabetes.

"Across all the different practices, we found that 15% to 20% of diabetes patients that we identified were based on lab data and they did not have a diagnosis code," he said. "Between 30% to 65% of patients had at least one laboratory care gap based on the clinical guidelines—such as an A1C test or micro-albumin test. Further, we saw that about 20% to 35% of patients had not seen their physicians for at least 12 months.

"After deploying this technology, 44% of people we contacted returned to the clinic, and half of them returned within 24 hours!" Chen said. "We track and document them with our technologies. For these patients, after we deployed the call, the next morning patients showed up at our PSC to get their blood drawn. This is a surprisingly high response rate, much higher than we anticipated.

"We attribute this response rate to the personalization of the contact by recording the doctor's voice," he commented. "This made a significant difference because providers told us their patients appreciated getting direct calls from their doctors telling them to come in. Also, the high response rate is partly due to the patient selection process. We call only those patients who are overdue for their care and most of the patients know they have a clinical need.

"Among the patients who did not come in, we identified that our data was not up to date on 35% to 45% of them. For them, we had what we call a 'bad data issue,' meaning we had the wrong phone number or the patient had moved away.

Only 7% of Patients Opt Out

"About 7% of patients opted out of the reminder service," he said. "This number was lower than we originally estimated because, before we instituted this program, we surveyed about 1,500 people in the general population, not the population that has health problems. For that survey, 48% of people told us not to bother them with such contacts.

"That survey of the 1,500 people in the general population told us that we were on the right track by reaching out to those patients with clinical needs and by personalizing the contacts with the physician's own voice, e-mail, or text," he explained. "In this way, we used data beyond genomics to deliver this targeted intervention." TDR

—Joseph Burns

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Lab Innovation Update

Sonic Adds More Value to Help Physicians Treat CKD Patients

ACO savings from managing chronic kidney disease totaled $12 million in year one, $26 million in year two

BUILDING ON THE LESSONS IT LEARNED by developing lab services that helped primary care physicians identify, diagnose, and treat diabetes patients in their practices, **Sonic Healthcare USA** was ready to do the same for another disease.

As explained on pages 10-16, Sonic wanted to go beyond simply reporting an accurate and timely lab test result. Instead, it wanted to leverage the value of its lab test data to help client physicians achieve better patient outcomes and contribute to lower costs of care—and be paid based on these benefits as they were realized.

This second chapter in Sonic's added-value story came quickly. After Sonic Healthcare USA achieved strong results in the diagnosis and treatment of diabetes for its client—a federally qualified health care clinic in New York—other Sonic clients became interested in working with Sonic to contact their patients who had gaps in care.

How to Reach Patients

"Once we deployed the technology for the first site, other clients—including ACOs and other payers—started coming to us with ideas about the patients they wanted to reach," said Philip C. Chen, MD, PhD, Sonic's Chief Healthcare Informatics Officer.

"Among those clients, there was much interest in managing patients with chronic kidney disease (CKD)," he explained. "With CKD, only about 12% of patients are diagnosed. Many are missed because these patients are asymptomatic, especially in the early stages."

The **National Institute for Diabetes and Digestive and Kidney Diseases** estimates that about 14% of the population has CKD. "This rate of illness and the cost of caring for these patients means there could be a significant source of revenue for clinical laboratories that have value-based contracts with payers seeking to identify and manage these patients," observed Chen.

To identify CKD patients, Sonic monitors the estimates of glomerular filtration rate (eGFR) by collecting two laboratory values at least three months apart. The GFR test measures the level of creatinine in the patient's blood to calculate the eGFR, a number that reflects how well the kidneys function.

"In one study of about 250,000 patients, researchers determined that—of those patients in stages 1, 2, and 3—about 90% were not diagnosed," Chen said. "Many times, even those in stages 4 and 5 and who were symptomatic, were still not diagnosed. Our own data show an almost identical distribution of the under-diagnosis rate.

"When establishing a financial arrangement based on identifying CKD patients, financial costs are compared with that of a normal person," he added.

"With a Medicare population, there is a $15,000 greater yearly cost for a patient who does not have that diagnosis versus a patient who does have the CKD diagnosis,"

Chen noted. "This substantial cost makes it important for ACOs, managed Medicare, and managed Medicaid plans to identify those undiagnosed patients with CKD and ensure that physicians follow up to document that diagnosis, so as to receive the appropriate financial attributions.

"Using our own lab-driven data, we work with ACOs and managed Medicare and Medicaid plans to help them manage CKD patients," he said. "During a meeting with one health plan in Texas, the administrators complained about how hard it was to identify CKD patients. To do so, they had about 20 nurses scour medical charts to find these patients. They understood the higher costs incurred by these undiagnosed patients, but didn't have an efficient way to identify them.

File with All CKD Patients

"Before I attended this meeting, I didn't know they had 20 nurses working on this specific project," he added. "I came to this meeting with the plan's data because we had cared for their patients for some time. Therefore, I was able to hand the health plan administrators a file showing all their patients who had CKD—both those with a diagnosis and those without a CKD diagnosis.

"This is the power of what we can do with laboratory data that adds value to both health insurers and physicians," stated Chen. "Sonic provides both the analytics and the patient-contact tools to bring those patients into the clinics so that they can be properly coded and managed."

"The next step in such a discussion is to use the data to get paid," Chen commented. "One approach we use is what we call a 'Healthcare Informatics and Preferred Provider Agreement.' CPL, our Texas-based laboratory, has such an agreement in place with a large, physician-owned ACO in North Texas that has a shared savings arrangement with Medicare.

"When we first started with them, they had 450 providers scattered over 135 different practices," he said. "Once we showed them our data and patient-contact tools, they wanted to integrate that information into their care management system. That allowed them to put the data into a central repository and use it to do additional analytics and interventions.

Lab Became ACO Provider

"Through a waiver designed for ACOs in the Medicare Shared Savings Program (MSSP)—we offered to deploy all these technologies at the ACO providers' practices—our lab was asked to join the ACO as a provider," noted Chen. "Today, we are one of the ACO's provider groups and our lab can deploy these technologies to help all of the providers achieve significant savings—savings that every provider, including our lab—can share in once it reaches a certain threshold.

"In the first year after deploying these tools, savings totaled about $12 million," he said. "But also in that first year, there was some noise in the data. So, despite the actual savings observed, the needle did not move much higher than was expected.

Savings of $26 Million

"That all changed in year two, when the savings jumped to $26 million, as a result of our program and other population health management tools the ACO deployed," Chen recalled. "Our lab thus got a very nice share of those savings.

"Under this contract, CPL gets paid with a traditional fee-for-service arrangement for laboratory tests," he concluded. "But we also got paid based on the savings we achieved with the technology we deployed and the value it delivered to patient care and reducing the cost of care. Most importantly, our lab is contributing value in ways that allow us to tap this different pile of money." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent weeks, **Apple** signed agreements with the nation's two largest lab companies to make their lab test data available on Apple's Health Record app. **Laboratory Corporation of America** was first to announce its agreement with Apple on Oct. 29. **Quest Diagnostics** issued its press release about its pact with Apple on Nov. 8. Apple says that its Apple Health record is now connected to 120 hospitals and provider groups, along with the two national lab companies.

MORE ON: *Apple Health app*

Apple seems to be building momentum with its Apple Health app. Early in the 2000s, both **Google** and **Microsoft** developed their own patient health record products. After much hoopla and a lack of consumer engagement, both companies quietly put those projects on the back burner. What has changed in recent years is the explosion in the number of devices consumers can buy, wear, and use that record different health and biometric data. Apple may have a strategy to use its Apple Health app as a way to help consumers pull all relevant data about their health and wellness into one place. This would then allow Apple to connect people to health resources, prescription drugs, and health similar services.

HORIZON NJ OPENS NETWORK TO QUEST

Horizon Blue Cross Blue Shield of New Jersey (BCBSNJ) will add Quest Diagnostics to its laboratory network in 2019. That ends Horizon's long-running exclusive relationship with Laboratory Corporation of America. During 2018, both **UnitedHealthcare** and **Aetna** ended national exclusive lab contracts and opened their networks to the two national labs.

ROCHE STARTS GLOBAL DIAGNOSTIC CONSULTING UNIT

Hospital Healthcare Europe reported that executives at **Roche Diagnostics** announced the launch of a new business division. **Roche Healthcare Consulting** will begin with 250 consultants. It will be led by Thai Viviani, who told the news outlet that the new consultancy "will focus on digital diagnostics and help laboratories, hospitals and other healthcare providers to 'optimize their performance.'"

TRANSITIONS

• Scott Nicholson is now Vice President of Sales and Support at **GenomeDx Biosciences Inc.**, of San Diego. Nicholson has held positions with **Miraca Life Sciences**, **Plus Diagnostics**, **Laboratory Corporation of America**, and **US Labs**.

DARK Daily
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DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how a shortage of anatomic pathologists in the United Kingdom is responsible for record-long treatment waiting times for cancer patients in England. Pathologists in the UK are asking the **National Health Service** to add more pathology training spots at medical schools.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, December 3, 2018.

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- ***Hospital Lab Uses Uber to Move Specimens: Why It Works, What It Costs, and What It Saves.***
- ***Health System Lab Consolidation Enters New Cycle as Administrators Emphasize Faster Service to Office-Based Physicians.***

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