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Special! Expanded Issue!

Exclusive Intelligence on Medicare Lab Competitive Bid Demo!

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...

R. Lewis Dark
Founder & Publisher

Is CMS Playing "Bait and Switch" in San Diego?

ATTEMPTING TO WRITE THE ASSESSMENT of the Medicare Clinical Lab Services Competitive Demonstration Project that you will read in this issue earned a unique distinction: since our founding in 1995, this has been the single most difficult story we have ever tried to explain to our clients and regular readers.

At the same time, it is likely to be one of the most important stories in the laboratory medicine profession in the past two decades. The **Centers for Medicare & Medicaid Services** (CMS) is now just six weeks away from collecting bids from labs hoping to preserve their access to Medicare fee-for-service patients in the San Diego-Carlsbad-San Marcos MSA (metropolitan services area).

You've probably read lots of news items about this competitive bidding demonstration. But what you haven't read is a serious, detailed critique about its design, its operation, and the ways it is likely to change how laboratories serve Medicare patients in the San Diego MSA. That's because it is a complex, subjective, and opaque scheme. CMS and RTI have delivered a demonstration project that lacks clear, objective standards. But that's only part of the story.

CMS is preparing to conduct a multi-step bidding auction. After opening the bids and evaluating the applications (using non-price criteria that are not objectively defined), it will begin a second round of bidding and negotiating with laboratories it has selected. Thus, labs will find themselves in an open-ended selection process. Not only do they not understand the criteria upon submitting their bids, but they don't know the precise terms and conditions of the provider contract CMS will require them to sign should they be selected.

Why all this obfuscation and not a transparent, objective bidding process? Smarter minds than I are dissecting the CMS/RTI scheme to implement the San Diego MSA pilot site in an attempt to answer that question. Many of us have come to a similar conclusion: CMS officials involved in designing the pilot demonstration had another agenda beyond meeting the Congressional mandate of finding a lower price while maintaining beneficiary access and service. Rather, their motive seems to use the demonstration as a way to extract bids from laboratories facing total loss of access to Medicare beneficiaries. CMS will then use these bids as a prototype for a new national Part B laboratory test fee schedule. If this proves to be true, then the laboratory industry is likely to feel like it was the victim of a CMS "bait and switch" tactic. TDR

San Diego Bid Demo Pilot Is Industry Turning Point

Forget the San Diego MSA demonstration pilot, these lab bids may be used to set national prices

CEO SUMMARY: In just six weeks, laboratories serving Medicare patients in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) will submit their bids to the Centers for Medicare & Medicaid Services (CMS). They may think they are bidding for access to patients in the San Diego MSA for the three-year duration of the demonstration pilot. But comments by a CMS official at the December bidders' meeting indicates that CMS may want to use these bids as the prototype for new national Part B pricing.

EARLIER THIS MONTH, OFFICIALS FROM the **Centers for Medicare & Medicaid Services** (CMS) took the wraps off their plan to conduct the Lab Competitive Bidding Demonstration Project, scheduled to take place in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) in 2008.

On December 5, over 100 laboratory directors and managers crowded into the bidders' conference conducted in San Diego by CMS and its contractor, **RTI International** (RTI), to learn the details of the impending demonstration project.

However, few attendees recognized the greater significance of that bidders' conference. They were present at an event that represents a turning point for the entire profession of laboratory medicine. That bidders' conference has set in motion a series of events that can be expected to change the laboratory industry in fundamental ways, both in San Diego and nationally.

This issue of THE DARK REPORT is devoted entirely to the Lab Competitive Bidding Demonstration Project for that reason. Laboratory administrators and pathologists in other regions of the United States need to understand why this bidding demonstration is a transformational event for the entire profession of laboratory medicine.

In the pages that follow are a series of intelligence briefings on different aspects of the San Diego MSA bidding demonstration, particularly from the perspectives of stakeholders that include Medicare patients, their physicians, and laboratory professionals. As you will learn,

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.)**

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

CMS and RTI developed this competitive bidding demonstration program with little informed input from the patient community, the physician community, and even the laboratory community itself.

Byzantine Bidding Scheme

By way of explanation, CMS and RTI have delivered a byzantine scheme for: 1) bid applications; 2) for the bidding selection process; and 3) for implementation of the bidding demonstration pilot. Overall, the requirements lack transparency, give CMS/RTI great subjective power and control over the outcome, and require a laboratory to enter the bidding process without a clear, objective understanding of the terms and conditions of the provider contract it will be asked to sign.

For laboratories serving the San Diego MSA, this alone poses a daunting challenge. They are being asked to prepare and submit bids as a pure act of faith, since there is no objective benchmark by which they can judge the final awards against their bidding strategy. By the way, that violates a fundamental principle of auctions and public bidding. Transparency and objectivity in bids submitted and bids awarded is essential. The lack of these attributes may be a sign that CMS doesn't believe it will be doing too many more regional competitive bidding demonstrations.

New Fee Schedule Prototype

Further evidence of that is the admission, by a CMS official during the December 5 bidders' meeting, that, even if the July 1, 2008 implementation of the San Diego MSA pilot demonstration is delayed or cancelled, the bids received on February 15 will give CMS the prototype for a new fee schedule it can submit to Congress. THE DARK REPORT is first to report this statement publicly and comment on what it is likely to mean.

That statement is the nuclear bomb that was dropped on the laboratory medicine profession while few were paying attention. It is an admittance by CMS that the value of the laboratory bidding demonstration project goes beyond experimenting with orderly ways to allow the market to price Part B laboratory testing services, as directed in the 2003 MMA legislation.

Rather, CMS bureaucrats are using the competitive bidding demo to give it a look at how the nation's two lab testing behemoths (along with smaller competitors) are willing to discount a menu of 303 routine tests. CMS will then turn around and use this information to propose a new national fee schedule to Congress, as early as 2009.

Lab Industry Turning Point

That is why THE DARK REPORT believes that the December 5 bidders' conference represents a turning point for the entire profession of laboratory medicine. Evidence is accumulating to indicate that a group within CMS has always intended that the laboratory competitive demonstration project be a Trojan Horse for collecting laboratory bids that it can use to overhaul the national Part B laboratory reimbursement system.

The laboratory medicine profession has a limited amount of time to respond to this new threat. Once bids are submitted on February 15, CMS/RTI will have achieved its goal of getting access to what the two national labs, and a handful of competitors, are willing to bid to retain access to Medicare patients. What follows in the San Diego MSA bidding demonstration may be moot if, by the end of 2008, CMS has used these bids to revamp the Part B laboratory reimbursement schedules for the 2009 federal fiscal year.

In the balance of this issue of THE DARK REPORT, there is coverage on many of the issues triggered by the current design and requirements for the competitive bidding demonstration project for the San Diego MSA. Labs have little time to act between now and the February 15 date for submitting bids. TDR

Analyzing Lab Bid Demo To Predict Its Outcome

San Diego-Carlsbad-San Marcos MSA is about to become a Medicare guinea pig

CEO SUMMARY: After two decades of study and preparation, the Centers for Medicare & Medicaid Services (CMS) is pushing the laboratory profession toward the first pilot site in the Congressionally-mandated Medicare Clinical Laboratory Services Competitive Demonstration Project. Designed to drive down the price Medicare pays for laboratory tests, the plan CMS described at the December 5 bidders' conference is likely to disappoint everyone—from patients and doctors to Medicare itself.

WHICH LABORATORIES WILL BE INVITED TO DANCE when federal healthcare officials select the labs they want to participate in the Medicare Clinical Laboratory Services Competitive Demonstration Project, scheduled to commence in San Diego in 2008?

THE DARK REPORT uses the term "select to participate" intentionally, because the bidding process the federal **Centers for Medicare & Medicaid Services** (CMS) and its contractor, **RTI International** (RTI), unveiled is not what most Americans would consider open, objective, transparent, and fair.

Complex, Obtuse, Subjective

To the contrary, CMS/RTI designed a bidding process that is complex, obtuse, and subjective—one that will lead to a predictable outcome about which specific laboratory organizations CMS selects as participants. That is the opinion of most informed experts who understand laboratory medicine and have studied the bidders' package released to the public and discussed at the December 5 bidders' conference in San Diego.

In the weeks since that conference, THE DARK REPORT has spoken to a cross section of pathologists, laboratory directors, and industry experts. These individuals have studied the bid documents, attended the bidders' conference, and in many cases, are actively working to craft a bid for their laboratory organization.

In situations like this, THE DARK REPORT would typically provide a simple, concise overview of the laboratory competitive bidding demonstration project. That would orient readers to the basics of this issue and give them context for the comments to follow. However, because CMS/RTI birthed such a labyrinthine concoction of qualifications, bidding requirements, and bid evaluation factors, there is inadequate space to communicate this information properly and succinctly.

In the spirit of brevity and to allow maximum attention to key issues, THE DARK REPORT suggests readers access the CMS Web site to read the full documentation on the Medicare Clinical Laboratory Services Competitive Demonstration Project. (*http://www.hhs.cms.gov/center/clinical/asp*.)

A number of other laboratory industry Web sites have developed descriptions of the three areas of the demonstration project: 1) requirements for bidding and how bids and the bid application are to be completed; 2) how CMS/RTI will score the bids and evaluate the bid documents to select winning labs; and 3) how the demonstration project will be implemented, beginning on the target date of July 1, 2008. Good starting points for finding commentary about the design of the bid demo are the Web sites of AAB, AACC, ACLA, ASCP, CAP, and CLMA, to name a few.

Observations & Criticisms

With those sites as resources, THE DARK REPORT would like to now present a series of observations and criticisms about the flaws different laboratory professionals have identified from their study of the bidders' package and their interaction with officials from CMS and RTI. These observations illustrate the lack of simplicity, fairness, transparency, and objectivity that are causing great concern among laboratories currently serving Medicare beneficiaries and their attending physicians in the San Diego MSA.

First are the strategic objectives of the laboratory competitive bidding demonstration project. The cover letter to the bidders' package CMS distributed at the bidders' conference on December 5, states that: "Section 302(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requires the federal Department of Health and Human Services to conduct a demonstration project on the application of competitive bidding for clinical laboratory services. The objective of the three-year demonstration is to determine whether *competitive bidding can be used to provide Part B clinical laboratory services at fees below the current Medicare payment rates while maintaining beneficiary access to laboratory services and quality of care*." (Italics by THE DARK REPORT.)

This statement of purpose has two strategic objectives. One is to use competitive bidding to lower the price Medicare pays for laboratory testing services below the current Part B fee schedule. Second is to maintain beneficiary access to laboratory services and quality of care.

There is solid consensus among those who have carefully studied the bidding documents and listened to CMS/RTI comments during the bidders' conference that the existing scheme is not likely to achieve either of its primary objectives. That is a disappointment, because Medicare beneficiaries in the bid demo site, their attending physicians, and the entire range of laboratory medicine professionals involved in delivering laboratory testing services in the San Diego MSA will bear the brunt of any significant failures resulting from this first demonstration site.

A primary failing in the bidding demo is that neither CMS nor RTI has recognized a basic fact: The medical specialty of laboratory medicine encompasses a wide range of diagnostic services. CMS/RTI ignores this important fact because of its single-minded focus for a way to conduct an auction that results in laboratories bidding lower prices than existing Part B reimbursement for an arbitrarily selected panel of 303 clinical lab tests.

Unity of Lab Medicine Ignored

Granted, CMS is correct in saying that these 303 tests represent 99% of what it pays for Part B lab testing services in the San Diego MSA. But, this ignores a basic fact about laboratory medicine: to work up a patient's case properly requires: 1) a combination of multiple lab test results, often performed in a cascade as the results from each assay are produced; 2) evaluation of these results in the context of that patient's health history by pathologists, chemistry Ph.D.s, and other laboratory specialists; and, 3) providing, as appropriate, direct clinical consultations about the patient with the referring physician.

issues are identified throughout this issue of THE DARK REPORT. *(See pages 9-11.)*

Moreover, it should be noted that the laboratory medicine profession has repeatedly identified these troubling aspects of the competitive bidding demonstration to CMS/RTI. But the government agency and its contractor, after acknowledging receipt of this information, failed to act to correct these issues, flaws, and problems.

Testing Without Payment

Another serious failing in the competitive bidding demonstration project is that it goes beyond denying existing laboratories the legal right to provide Part B lab testing services to Medicare fee-for-service (FFS) beneficiaries. Laboratories defined as "non-providers" following the selection of the winning bidders will be forced to provide lab tests to Medicare beneficiaries living in the San Diego MSA without any hope of reimbursement.

By intent, CMS will expect non-winning labs to perform testing for which the Medicare program will not reimburse! At the bidders' conference on December 5, CMS officials were asked how "non-participating" laboratories would handle the specimen of a San Diego Medicare patient who showed up in their laboratory.

On December 21, CMS distributed an e-mail titled "Follow-up From Bidder's Conference" and answered that point as follows:

> ***Question 10:*** *Can a laboratory refuse to provide a laboratory test for a Medicare beneficiary residing in the CBA?*
>
> ***Answer 10:*** *A laboratory that is enrolled as a Medicare supplier cannot legally refuse to provide services to a beneficiary based on payment.*

Laboratories are keenly aware that Medicare patients are creatures of habit. Laboratories excluded by the Medicare program from providing testing to Medicare beneficiaries in the San Diego MSA know that elderly patients, having come to their lab's patient service center for years—even decades—will be unaware of the lab's changed status as a non-approved provider of Part B laboratory testing services for the demonstration pilot. CMS/RTI are putting a huge burden on labs excluded as providers in the San Diego MSA demonstration pilot. These labs must redirect an often feeble, disoriented Medicare patient to a lab approved to do the testing. If they respond humanely and in the best interest of the patient at that moment, the lab will collect the specimen and perform the tests, with the full knowledge that Medicare will not reimburse it for this act of clinical service and human kindness.

It should be noted that the majority of Medicare patients, made aware of this situation, would consider it un-American, unfair, and a gross violation of the principles upon which this country was founded. After all, government Medicare officials are taking the long-standing "any willing provider" philosophy for Medicare Part B FFS and subverting it into an artifice where it subjectively chooses which labs are "in" and which labs are "out." It then uses the club of the law to force the "out" labs to perform testing with no hope of reimbursement!

This smacks of involuntary servitude, because the Medicare program will compel that lab to perform a service for free. Maybe involuntary servitude is not the correct legal term in this instance, but most Americans would expect that, if a private health insurer tried this same scheme, courts would overturn it immediately. It would be interesting to see if this competitive bid demo requirement would stand up in court if it were to be litigated.

Serious Flaws In Bid Demo

These opening observations about the Medicare Laboratory Competitive Bidding Demonstration Project illustrate serious flaws in both the philosophy that guided its creation and the motives of CMS officials in its execution. Intelligence briefings on the following pages will highlight other disturbing issues of the San Diego pilot bidding demonstration. TDR

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Anticipate Access/Service Decline for S.D. Patients

Three levels of access to lab testing services not addressed in design of the lab bidding demo

CEO SUMMARY: In its primary push to use the Medicare Laboratory Competitive Bidding Demonstration Project as a tool to drive down the price Medicare pays for Part B laboratory testing services, CMS is giving secondary attention to patients' needs. In particular, CMS seems to place little value on the multi-year relationship and loyalty many elderly patients have with their existing laboratories, nor on the professional relationship the patients' doctors have with their laboratory providers.

THERE WILL BE SERVICE DISRUPTIONS and ample confusion for significant numbers of fee-for-service Medicare patients in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) when CMS implements the Medicare Clinical Laboratory Services Competitive Demonstration Project on or after July 1 next year.

Collectively, Medicare beneficiaries are intense users of healthcare, particularly of laboratory testing. For example, it has long been accepted that a "commercial population" of patients under Medicare age will use laboratory tests at the average rate of almost three tests per year per person. A population of Medicare beneficiaries uses tests almost three times as often, at an average of about nine tests per year per person.

High Test Utilization

The San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) has a Medicare fee-for-service (FFS) population of 209,242 people. The federal **Centers for Medicare & Medicaid Services** (CMS) released a 2006 lab test utilization figure for the 303 tests in the bid requirements that totals 1,724,727 for this population. This works out to be approximately 8.2 lab tests per Medicare FFS patient per year in the San Diego MSA.

This remarkable statistic should not go unnoticed by health policy makers and elected officials responsible for the Medicare program. Of all the healthcare services that Medicare beneficiaries get each year, laboratory testing is one that is used intensively—for all the right reasons. These facts should also cause CMS to proceed with caution. Given that such a large proportion of the Medicare population uses laboratory testing every year, policy makers should be wary about disrupting elderly patients' access to lab tests and what is acknowledged to be a smooth-running delivery of laboratory services in the San Diego MSA.

Further, it should be noted that, even though Medicare beneficiaries are intensive users of laboratory testing services, laboratory testing is one of Medicare's best bargains and provides cost-effective clinical leverage to physicians. Typically labo-

ratory testing services are about 3% of the total Part B spending, but are used by physicians in between 60% and 70% of their diagnoses and decisions on how to treat patients!

These dramatic facts illustrate why access to laboratory testing for Medicare patients is vital to maintaining their health and advancing treatment for those individuals with multiple maladies. As laboratories well understand, "access" works at three levels. In the San Diego bidding demonstration, there is the potential that this access will be disrupted and denied in significant ways.

➤LAB ACCESS LEVEL ONE:
Full Service and STATs 24/7

One level of access is the ability of the Medicare patient, and his/her physician, to work with a laboratory that offers a full menu of lab tests and is capable of performing STAT testing when needed. That means during health emergencies, the laboratory has a service network to receive a STAT specimen, perform the test, and deliver the results to the patient's physician in as little as an hour.

In the San Diego demonstration project, the bidding requirements make it likely that some existing local and neighborhood laboratories, including community hospital labs that provide testing services to doctors' offices across the street from the hospital, will be excluded from providing for Medicare beneficiaries.

➤LAB ACCESS LEVEL TWO:
Personal Relationship Between Doctor & Lab For Consultations

The second level of access to laboratory testing for the Medicare patient involves his/her physician or caregiver. Does the clinician have a relationship with the laboratory and the ability to quickly reach the pathologist, Ph.D., or laboratory scientist who supervised the testing and reviewed the patient's results? The professional consultation between the patient's physician and the pathologist or other laboratory scientist is an integral part of the lab testing process. Often, when the attending physician has the pathologist or other lab professional review the lab results of the most recent test in the context of the patient's earlier test results and medical history, the pathologist can guide the clinician toward a diagnosis and clinical action that was not immediately obvious to the attending physician.

This element of laboratory medicine often goes unnoticed. Yet, it is why a large number of physicians prefer to work with their local laboratories or their hospital's laboratory outreach programs and reject using out-of-town labs.

These physicians recognize that having a personal relationship with local pathologists and laboratory scientists contributes to continuity of care. This relationship often makes a vital difference when a single lab test result is ambiguous to the physician, leading to a professional consultation with the pathologist to review the patient's history and cumulative record of lab test results.

➤Ignore Clinical Relationships

It is disturbing that CMS/RTI has made little or no allowance for this ongoing clinical consultation that occurs between the referring physician and his neighborhood pathologist or laboratory scientist in its design of the San Diego bidding demonstration project. Further, such consultations are frequently the case when the community hospital laboratory provides lab testing services to the physicians in medical offices across the street from the hospital. In these cases, the Medicare patient's inpatient, outpatient, and outreach testing lab results exist in a single record, giving the doctor immediate access to the patient's complete and comprehensive lab test history—often extending back many years.

Further, as the physician makes daily rounds of his Medicare patients in the

hospital, he/she often sees the pathologist, even casually in the cafeteria or walking in the halls. During these moments, doctor and pathologist discuss cases. Often, the pathologist is very familiar with the Medicare patient because he/she has been evaluating biopsies and participating in tumor board sessions involving the patient's case, for example.

Because the bidding demonstration requirements are written in a restrictive way that favors large national laboratories over local labs and community hospital labs, physicians treating Medicare patients in the San Diego MSA are at risk of losing access to these reliable community resources and clinical assets.

LAB ACCESS LEVEL THREE:
Geographical, Physical, Personal

The third level of access to laboratory testing services is geographical, physical, and personal. Does the patient's choice of laboratory have a patient service center (PSC) or specimen collection center close to where the Medicare beneficiary lives or spends time? Does the PSC offer easy access for a Senior Citizen with limited mobility? For example, the PSC may be in the same office building as the patient's physician, or a short walk from a parking lot without stairs to negotiate.

Finally, there is access in the personal sense. A Medicare patient may have been visiting the same laboratory PSC for years, even decades. Many Medicare patients are tested with such regularity that they become good friends with the phlebotomists and other staff at the PSC. In some cases, their laboratory of choice has a skilled phlebotomist who can perform the venipuncture in a most comfortable way or successfully perform difficult blood draws. In these cases, a Medicare patient will be highly loyal to these specific laboratory professionals because their skills—and their friendship—make the difficult, painful process of venipuncture easier to bear.

Discomfited Medicare beneficiaries in the San Diego MSA can become a noisy constituency for elected officials. Some rough calculations demonstrate the scale of the turmoil and disruption that could potentially happen in the lives of these elderly patients.

First, assume that the two national laboratories already hold about 80% of the Part B fee for the testing market in the San Diego MSA. That means they currently serve approximately 167,000 of the 209,000 Medicare FFS beneficiaries.

If the bidding procedure ends up excluding the local lab in Oceanside (**Internist Laboratory**, see pages 12-15) and most of the hospital laboratories currently serving Medicare FFS beneficiaries in the San Diego MSA, this means as many as 41,800 elderly patients could be forced to begin using other laboratories.

As a result, each week after the July 1 implementation takes place, physicians may have to tell an estimated 1,000 to 2,000 Medicare beneficiaries that they must use a different laboratory. This starts a process that requires the patients, and their loved ones or caregivers, to find the new laboratory specimen collection sites and to have strangers draw their blood or collect their specimens.

Lots of Disruption Ahead

With as many as 41,000 elderly patients being directed away from long-standing laboratory relationships in the San Diego MSA demonstration project, and with their attending physicians forced to break the same long-standing laboratory relationship, there will be lots of disruption. More important, the laboratory medicine profession recognizes the potential for patient harm every time existing and satisfactory laboratory relationships are disturbed because of laboratory acquisitions, mergers, or consolidation. Thus, the possibility of direct patient harm is a real threat. TDR

Local San Diego Lab Fights Bias In CMS Bid Demo

➤San Diego's only local lab illustrates why CMS/RTI's scheme intentionally excludes small labs

➤➤CEO SUMMARY: Meet Internist Laboratory of Oceanside, California. For 18 years, its owners, Gary and Christine Stevens, have provided a high level of laboratory testing services to office-based physicians in Northern San Diego County. Now Internist Laboratory is the perfect poster child for all the flaws and bias built into the Medicare Laboratory Competitive Bidding Demo. If denied access to serving Medicare beneficiaries for three years, it will face a financial crisis with no solution.

IT'S TIME FOR THE LABORATORY PROFESSION AND CMS POLICY MAKERS to meet the perfect poster child to illustrate the shortcomings in the Medicare Clinical Laboratory Services Competitive Demonstration Project. It is **Internist Laboratory** of Oceanside, California, in northern San Diego County.

Owned by the husband and wife team of Gary and Christine Stevens, Internist Laboratory is a perfect example of the local laboratory organized to provide high levels of personalized service to patients physicians, and providers in its community. This focus on service and emphasis on meeting the unique needs of its local healthcare community allows it to compete and survive against the largest regional and national lab companies.

➤Wants To Serve Medicare

Yet, despite the assurances of officials from the federal **Centers for Medicare & Medicaid Services** (CMS) that the San Diego-Carlsbad-San Marcos demonstration pilot will be local-lab friendly, the Internist Laboratory example provides compelling evidence that the bidding requirements will effectively exclude them as providers of laboratory testing in the Medicare demonstration pilot.

"We have only 10 employees and a consulting pathologist," said Gary Stevens. "Internist Laboratory performs more than 1 million tests each year and has been in business here for 18 years. We serve office-based physicians in the Tri-City area of Vista, Carlsbad, and Oceanside, California, and continually get referrals from physicians in these communities."

"We service many patients with special needs, in that the caretakers bring them to our lab's service centers," stated Christine Stevens. "However, we do not contract with nursing homes or long-term care facilities.

"We are also significantly less expensive for cash-paying patients who may not have insurance than the two large national labs," she explained. "For example: we charge $20 for a lipid panel and other labs charge $89. Our price for a CBC is $12; other labs charge $44. Our draw fee is $6, and other labs charge $39. In this area, we are known for outstanding service, yet we are not more expensive for cash-paying

patients than the large labs. We are actually much less!"

Gary Stevens added, "We compete on service. Doctors and patients come to us because they like our personal service. Our presence in the local community makes a difference. For example, we often collect specimens and provide test results on the same day. This is particularly important for oncology patients who must have their results before they can get chemotherapy."

However, none of these service attributes will help, based on Gary Stevens' study of the competitive bidding demonstration requirements. "Basically, if lowest price is the major criteria, then we can't compete against **Laboratory Corporation of America** or **Quest Diagnostics Incorporated** in this Medicare lab demonstration," he said.

A Question Of Survival

Christine Stevens agreed, saying, "Fewer labs in the market will not necessarily mean less expensive costs and will probably mean lower quality service. In regards to Medicare, we accept assignment and receive the same amount as any other lab, large or small. We would be happy to continue on this basis. Yet, if we are not a winning lab, and Medicare prohibits us from serving Medicare patients, we cannot continue to operate since the majority of our patients are Medicare beneficiaries."

"The lowest price is not the best way to evaluate how we contribute to quality care for Medicare beneficiaries in our community," added Gary Stevens. "Until now, we have been competitive because our service is so much better. Plus, we're the only lab serving this community that can actually perform lab tests in this area. The next closest lab is 45 minutes away, and that's a LabCorp facility. Our location is convenient, dead center in the heart of the Tri-City's medical area. That location allows us to provide the quickest and most affordable laboratory testing in North County San Diego.

"Depending on the day and the traffic, it often takes longer than 45 minutes to get to the next nearest lab," Steven explained. "During the wild fires this fall, labs at both LabCorp and Quest were closed for a time. We were the only lab here in north county that could do testing. In so many ways, our service is much better, in part because we baby the patients and the doctors. Frankly, we survive on service and quality.

65% of Volume Is Medicare

"That's why we are so concerned about our ability to participate in the Medicare laboratory competitive bidding demonstration," he noted. "Currently 65% of our volume comes from serving Medicare patients. If we are not selected as a winning bidder, it will go badly for us. Not knowing where the price cuts are going to come or what percentage they're looking for, we just don't know what effect it would have right now. And since we're bidding against LabCorp and Quest, there's no way to know how we'll come out of this because this competitive bidding program removes service and quality out of the mix. We'd be living on 35% of our volume. That won't pay the bills."

Another requirement of the bidding process creates additional challenges. "Despite the fact that we perform about half of the 303 tests here in our own laboratory, I must submit a bid price on all 303 tests," explained Stevens. "It means my reference labs must provide me with prices on those tests for Medicare patients.

Depending On A Competitor

"I've talked with LabCorp, and they say we'll be getting prices, but right now we have less than 45 days until the bid is due," he worried. "If they drag their feet too long, we're at their mercy. There are not that many labs down here, so I'm not sure why they wouldn't call back.

"We've also contacted Quest Diagnostics to get prices we can use to plan our bid," Stevens said. "I've put in two or three calls to

them, but no one at Quest has yet returned my calls. We are required to bid on 303 tests but we do only about half of those here in our lab. If reference labs won't call me back, I don't know what to charge.

"The bidding demonstration project is set up in a way that makes local labs dependent on Quest and LabCorp— because they do the reference and esoteric tests," Stevens commented. "They are in a control position because our bid depends on what prices and volume they give us. And, it was established at the CMS bidders' conference that they don't have to give us the same price that they bid. They can give us a straight bid, for example, and then take 5% or 10% off their bid and we could be eliminated just on that.

"So, at the bidder's conference, I asked the CMS and RTI people: Why is this bidding program set up to eliminate competition? They had no answer," he said. "Their response was only that I should send them an e-mail with any questions that I had. It is frustrating that the Medicare program has designed the demonstration pilot to make it impossible for small labs to participate as a provider."

Poster Child For Problems

The comments of Gary and Christine Stevens show why Internist Laboratory is the perfect poster child for exposing the built-in bias against small labs participating in the laboratory competitive bidding demonstration project about to occur in the San Diego MSA.

One, CMS and RTI have established bidding requirements that make it virtually impossible for Internist Laboratory to submit a bid with discounted prices that would qualify it as a winning bidder under the announced formula. Instead of being asked to price aggressively the 150 or so tests it does perform internally, it must submit prices for 303 tests—and for 150 of these tests, it must rely on prices provided to it by either or both the national labs.

As of press time, neither of these lab companies, in their role as reference labs, had provided a price list for bidding purposes to Internist Laboratory. Why would a government agency design a bidding process that makes small independent laboratories dependent on getting discounted bid prices from their largest competitors?

Two, the CMS/RTI bidding requirements fail to recognize the continuity of care Internist Laboratory provides to Medicare patients in the north county area. If Internist Lab is not selected as a winning bidder, both Medicare beneficiaries and their referring physicians lose this continuity of care in lab testing.

Asking Tough Questions

Third, by establishing bidding barriers for such local labs, CMS/RTI has increased the odds that this independent laboratory will face financial failure. The likelihood of that outcome increases because 65% of the patients served by Internist Laboratory—the only laboratory based in the Vista, Carlsbad, and Oceanside area—are Medicare beneficiaries.

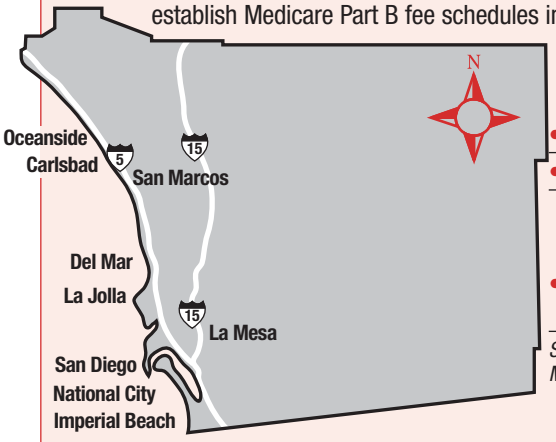
As a poster child for the bias against smaller local labs in the Medicare demonstration project, Internist Laboratory graphically demonstrates how the bidding process will put Medicare patients at a disadvantage. More to the point, Gary and Christine Stevens have worked 18 years to build a modest business focused on serving the needs of patients and physicians in Vista, Carlsbad, and Oceanside. Why should a government agency now push them to the point of bankruptcy?

Stevens certainly deserves answers to the questions he's asking. And here's another one that should also be answered: Why does any large purchaser, including Medicare, want to exclude two small businesspeople who have survived in America's toughest managed care market for 18 years by offering Medicare patients local, personalized, high quality services? TDR

Contact Gary Stevens at 760-724-9231 or Internistlab@sbcglobal.net.

San Diego-Carlsbad-San Marcos MSA to Be Site of First Medicare Competitive Bid Demo

AS THE FIRST PILOT SITE for the Medicare Laboratory Competitive Bidding Demonstration Project, the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) is a unique market. It has a high proportion of managed care contracting relative to other regions of the United States. Office-based physicians are served primarily by the two national laboratory companies, along with a limited number of independent lab companies and a handful of hospital laboratory outreach programs. The basic calculations below show how the dominance of the two national labs makes them the logical winners in the competitive bidding demo. The question is what strategy each national lab will use to construct its bid, since each is aware of how these prices may be used to establish Medicare Part B fee schedules in other regions or nationally.



San Diego-Carlsbad-San Marcos MSA
(17th largest MSA in United States)

Looking at the Numbers

• Total MSA population	2,941,454
• Total Medicare beneficiaries	360,312
Fee for Service	209,242
Medicare Advantage	151,070
• Total 2006 Medicare Part B Lab spending in San Diego	$21 million

Sources: U.S. Census Bureau, Centers for Medicare & Medicaid Services (CMS), other sources.

Labs providing testing to office-based physicians in the San Diego MSA:

- LabCorp (San Diego)
- Quest Diagnostics (San Juan Capistrano, West Hills)
- Internist Lab (Oceanside)

Other California labs with a presence:

- Westcliff Medical Labs (Santa Ana)
- Primex Clinical Labs (Van Nuys)
- Physicians Automated Lab (Bakersfield)
- Advanced Medical Analysis (Monrovia)
- Bio-Data Medical Lab (Montclair)

Hospital Laboratory Outreach Programs:

- Sharp HealthCare (San Diego)
- Scripps Health (San Diego)
- Alvarado Hospital (La Mesa)
- Paradise Valley Hospital (National City)
- Tri-City Medical Center (Oceanside)

What's the potential for disruption to beneficiary access and Medicare cost savings?

1. Assume LabCorp and Quest together hold 80% of the Part B lab test market in San Diego MSA.
2. Assume that represents 167,394 (80%) of Medicare FFS beneficiaries in the San Diego MSA.
3. That leaves 41,848 (20%) Medicare FFS beneficiaries who may possibly need to change labs (if their existing laboratory provider does not submit a winning bid.)
4. Assume $21 million in Part B lab spending in San Diego MSA during 2006.
5. Each 1% bid under the existing spending level represents potential savings to Medicare of $210,000.
6. If winning bids reduce total spending by 5% or 10% below the 2006 actual, that would generate $1.05 million and $2.1 million in annual savings, respectively.

Numerous Issues Identified With Bid Demo's 303 Tests

National expert in coding and billing predicts some confusion during the pilot demonstration

CEO SUMMARY: One experienced expert in billing and coding was surprised at the list of 303 tests to be included in the Medicare Laboratory Competitive Bidding Demonstration Project. He notes that the list of 303 tests includes a number of codes and descriptions that are not consistent with CPT codes used by laboratories to prepare and submit claims to Medicare. This may cause some confusion for labs that plan to bid for the San Diego demonstration pilot site.

William K. Dettwyler, M.T., is the Procedure Code Analyst for Codus Medicus of Salem, Oregon. Dettwyler has extensive experience in laboratory coding and billing. When Oregon reformed its Medicaid program in the mid-1980s, Dettwyler had a lead role in designing the laboratory codes and billing guidelines for the Oregon Medicaid program. He also worked for many years as a laboratory consultant to the Medicare Carrier ***Aetna****, when it was the Part B Payer for Oregon.*

By William K. Dettwyler, MT

As many pathologists and lab directors are learning, the Laboratory Services Competitive Bidding Demonstration Project that the federal **Centers for Medicare & Medicaid Services** (CMS) is foisting on the lab profession is confusing, unnecessarily complex, and not likely to achieve its objectives.

One aspect of the bidding requirements that I find particularly troubling is the list of 303 lab test procedures that are the subject of the bidding demonstration. This list of procedures and tests appears to have been put together in a disordered manner. Individuals with experience in coding and billing for laboratory services will recognize that this list is not how the Medicare program currently requires laboratories to prepare and present claims for laboratory services under the Part B schedule.

Derived From Payment Data

Rather, this list of 303 tests appears to be developed by CMS from its payment data. Because of that fact, this bid demo test list presents some issues that will complicate CMS's efforts to accurately process, pay, and record claims activity during the three-year period of the pilot demonstration project. For laboratories that participate in the demonstration project, it will require extra care in preparing bids and filing accurate claims.

One obvious point to make is that laboratories are required to submit claims to CMS with a CPT/HCPCS code that is approved by the **American Medical Association** (AMA) and/or CMS. Not every test identification number provided by CMS on the list meets this criteria. There are a number of tests identified by

ATP (Automated Test Panel) numbers in the list of 303 tests. ATP numbers are not used by laboratories to submit claims to Medicare. Rather, CMS uses these ATP numbers in its payment system.

In the bidding documents, CMS acknowledges this. It explains how laboratories must unbundle the comprehensive panels to prepare bids for tests that are identified by the ATP numbers. That is why I believe the government used its payment system to generate this list of tests. It is likely that the payment system was also the source of the utilization numbers for each test that CMS provided in the bidder's package.

If this is true, it is significant for another reason. It is evidence that the government is not capturing claims by the CPT codes used when a laboratory submits a bill for payment. Instead, the government is using its payment system to track utilization—and to produce this list of 303 tests. Essentially, labs are talking to Medicare in CPT code language and using their CPT coding to track their utilization. Meanwhile, it appears that Medicare tracks utilization by using its payment system numbers, including the ATP codes.

Answer To Another Question

If CMS does lack the ability to track, in detail and with acceptable accuracy, the number of claims submitted by CPT codes, along with the number of claims paid and denied, this fact might also answer another question that laboratories have asked about the bidding demonstration requirements.

I've heard that there was intense discussion at the bidders' conference in San Diego earlier this month about utilization numbers. Utilization numbers are an important factor in the bidding requirements. Each laboratory bidder must provide both a price and a specific volume number for each test that it can provide during the demonstration period.

CMS will aggregate the test volumes of individual bidders as it works from lowest bidder to higher bidders. As soon as it has the needed test volume to match its estimated utilization number for the San Diego MSA, it will close the bidding.

For this reason, laboratories are keenly interested in how CMS and its contractor, **RTI International** (RTI) determined three components: 1) actual utilization numbers for 2006 in the San Diego MSA; 2) the actual number of denied lab test claims in the San Diego MSA for 2006; and, 3) the details of the "trending factor" calculations CMS/RTI used to determine utilization growth.

What Is Denial Rate?

Apparently, many labs asked CMS to make this data public. Further, labs were keenly interested to get information about the rate of claims denials for Part B laboratory services. They pointed out that the denial rate may be as much as 25% and the volume of these unreimbursed tests performed for Medicare beneficiaries needs to be part of the cumulative utilization figure included in the bidding demonstration for the San Diego MSA.

It was reported that CMS officials declined to make that information available. There could be a good reason why CMS refuses to provide such data: it doesn't have it! If CMS primarily relies on its payment system for utilization data and other information, then information from denied claims handled by processors at the Medicare carriers may not be captured and available to CMS.

Returning to the list of 303 tests, I noticed a number of tests were listed that most laboratories seldom perform anymore. One example is "8100-Urinalysis, non auto w/scope." I was surprised to see 6,327 tests reimbursed for this in 2006. Few providers are doing manual UAs. My suspicion is that these may represent paid claims to providers, including physicians' offices, using the wrong code.

However, the fact that CMS is including a number of tests on the list of 303 that

are no longer offered by most clinical laboratories, large and small, indicates that some of this utilization volume probably originates in physicians' offices or physicians' office laboratories (POLs). Laboratory bidders should be entitled to learn how much of the lab test volume CMS is reporting is actually sourced from testing done in doctors' offices and their POLs.

Another test on the list deserves comment. CMS has included "36415-Routine Venipuncture." Venipuncture is a surgical procedure in the CPT book and is not a laboratory analytical procedure. A great number of healthcare providers perform venipuncture. It is inappropriate for this procedure to be included in a list of laboratory tests to be included in the bidding demonstration project. CMS and RTI should explain their motivation for including this non-laboratory procedure on the list of 303 clinical laboratory tests.

These are some observations about why there is likely to be confusion and problems with implementing the list of 303 lab tests as described by CMS. Based on my years of experience with coding and billing, it is disappointing to see CMS and RTI deliver such a poorly-designed demonstration project. Further, since the mid-1990s, the constant drumbeat by CMS has been for labs (and all providers) to file accurate claims.

Lacking Same CPT Codes

In summary, it is a major contradiction to longstanding CMS policies for its competitive bid project to include a list of 303 tests which do not carry the identical CPT codes and descriptors as labs use on the claims they file. In fact, labs are constantly told by the government, the OIG, and independent experts that they should not file claims and use codes that do not exist in the CPT or HCPCS billing guides. It does not seem auspicious that labs are now being asked to submit bids and sign contracts for tests identified with CMS's internal payment labels and not by the appropriate CPT/HCPCS codes.

This confusion should not to be tolerated in a bidding demonstration project that should be transparent and easy to understand by the laboratory personnel expected to bid on these tests. When the bid documents indicate a failure to understand the issues involved in processing lab specimens, how can CMS expect labs to respond correctly? The results will be confusing, causing the project to be challenged and not of any meaningful value.

Built on an Archaic System

Finally, it is my opinion that, if instituted nationally, competitive bidding for lab services would reduce the number of operating laboratories over a few years. This would happen because smaller, local laboratories would be financially squeezed, if not outright excluded by the bidding process in each region.

What would emerge is a "laboratory megasystem", dominated by as few as one, but probably not more than three or four huge laboratories. Soon thereafter, there would be little competition in the laboratory industry and the government would be at the mercy of its own solution. It could not afford to discipline a lab that is the only one serving a region or shut it down if there were problems.

Such a laboratory megasystem would be able to influence bidding, as there would not be other labs of equal or comparable size to compete with it. Florida's Medicaid program recently proposed an exclusive contracting system similar to the one CMS is trying in San Diego and it was such a disaster that it was called off. *(See TDR, January 5, 2005.)*

The stakes are high for Medicare patients, their physicians, and laboratories. That is why it is imperative for CMS to get it right before it begins restricting small labs simply to achieve lower prices through the economies of scale of the largest lab companies. TDR

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Three Strikes Against CMS Before Bid Demo Begins

CMS fails to engage voices of patients, of physicians, of lab profession in demo's design

CEO SUMMARY: There's a touch of irony in the fact that the Medicare program is a national leader in encouraging hospitals, physicians, and other providers to pay greater attention to the voice of patients. Yet within the Centers for Medicare & Medicaid Services (CMS), officials tasked with developing the laboratory competitive demonstration project seem to have ignored the voices of Medicare beneficiaries, the physicians who serve them, as well as the laboratory medicine profession.

IN TODAY'S HEALTHCARE WORLD, Medicare asks hospitals, physicians, and other providers to involve patients in efforts to raise the quality of care, reduce medical errors, and lessen the cost per episode of care.

To ensure that hospitals and physicians are listening to the voice of the customer, health accreditation guidelines require providers to survey patients following their treatment. Accreditation requirements direct hospitals and physicians to act upon patient satisfaction surveys and demonstrate how this information was used to improve performance at the next accreditation inspection. The Medicare program is a national leader in pushing hospitals and physicians to reach out to patients, understand their concerns, and take active steps to improve the patient experience and quality of care.

Yet, at the same time that the Medicare program is making a major priority of listening to the voice of the patient, officials at the **Centers for Medicare & Medicaid Services** (CMS) tasked with creating and implementing the laboratory competitive bidding demonstration project have deliberately excluded the voices of their customers during their design process. It is an irony that should not be lost on senior administrators at CMS, nor their Congressional overseers.

Meeting Constituents' Needs

This is particularly true since many Americans view CMS, and most government agencies, as a service bureau, chartered to provide public services which meet the needs of its constituency, as defined by enabling legislation. In this role, CMS must consider the voices of its customers.

In the case of the Medicare Clinical Laboratory Services Competitive Demonstration Project, Congress established two general objectives. One objective is to determine whether "competitive bidding can be used to provide Part B clinical laboratory services at fees below the current Medicare payment rates" (from CMS letter dated December 5, 2007). The other objective is to achieve these lower fees "while maintaining beneficiary access to laboratory services and quality of care" (also from the CMS letter dated December 5, 2007.)

These exact quotes from the CMS letter do not give either goal primacy at the expense of the other. Thus, it has surprised many in the laboratory industry that the form and structure of the laboratory competitive bidding demonstration project for the San Diego MSA indicate a clear lack of attention to issues that will affect Medicare beneficiaries, their attending physicians, and the laboratories, pathologists, and Ph.D.s that provide them with diagnostic testing services and consultations.

...count one strike against CMS/RTI. There is little or no evidence in the public domain that its preparation for the competitive bid demonstration project involved serious discussions with patients and their advocates.

CMS has an obligation to consider the interests of Medicare beneficiaries and how the laboratory competitive bidding demonstration project might negatively affect their care or cause them to lose access to familiar, favored, and high-service laboratory providers. CMS/RTI does not seem to have consulted with beneficiaries or those who can speak for them.

No Public Information

The story on pages 9-11 provides a list of important issues that will directly affect patients, assuming that CMS proceeds with the competitive bidding demonstration project as currently structured. If CMS and RTI convened a representative panel of patient advocates and explored how its plans to limit the number of laboratory providers would positively or negatively affect Medicare beneficiaries, that information has not been widely circulated.

Thus, count one strike against CMS/RTI. There is little or no evidence in the public domain that its preparation for the competitive bid demonstration project involved serious discussions with patients and their advocates. If true, CMS is proceeding to implementation lacking the patient's perspective on how the proposed changes in laboratory service providers might have a negative affect on Medicare beneficiaries in the San Diego MSA.

Next, did CMS/RTI take up all the ways that the laboratory competitive bid demonstration project could cause problems for physicians, providers, and facilities such as hospitals and nursing homes? Again, there is little public evidence that CMS called together a representative panel of physicians, hospital administrators, long-term care (LTC) facility managers, and similar healthcare professionals to understand how they could be negatively affected. If it lacks this input and guidance, is CMS/RTI justified in telling Congress and the American public that their scheme for implementing the competitive laboratory bidding demo in San Diego MSA will not interrupt or disrupt patient care in harmful or negative ways?

Forced To Use A Different Lab

Every pathologist has direct knowledge of episodes where, as a physician changed from using one laboratory to another, there were identified failures that affected patient care. These problems are invariably associated with physicians being forced to use laboratories that are not their preferred choice or because of new policies as a consequence of laboratory mergers and acquisitions.

Another source of such problems is the use of exclusive contracts by private payers (including Medicare Advantage plans) to restrict all but contracted labs from providing services to their beneficiaries. Breakdowns in patient care can result from something as simple as not understanding the new laboratory's reference ranges (because the new lab uses a different methodology and/or reporting format from the previous laboratory).

Further, it is well known that physicians consistently complain to private insurance companies about being forced to use laboratories that are not of their choosing. Yet that is precisely what CMS/RTI is preparing to do to physicians in the San Diego MSA.

All of these negative experiences make it appropriate to ask this question. Has CMS/RTI engaged stakeholders from the physician and provider community to identify their concerns and design a bidding formula, evaluation and award procedure, and implementation process that avoids disruption to the physicians' clinical practice and operational work flow?

Based on the available public evidence, the answer to that question seems to be "no." Thus, for failure to directly engage physicians and providers for feedback and guidance on this competitive bid demo, tally another strike against CMS/RTI.

That brings us to the third class of customer that CMS/RTI has a legislative directive—and ethical imperative—to consider. It is the laboratory medicine profession. The term "laboratory medicine profession" is used deliberately. What most elected officials in Congress do not realize is that laboratory medicine is a complex medical specialty. The body of clinical knowledge in this field is immense. The number of specific assays available to support clinical care is climbing toward 5,000.

Carving Out 303 Lab Tests

CMS/RTI proposes to carve out 303 specific lab tests because these 303 tests happen to represent 99% of what Medicare spent to pay Part B claims for beneficiaries in the San Diego MSA in fiscal 2006. But the bidding formula and the process used to select "winning" laboratories fails on several counts. Those failures are documented in other publications and public Web sites, and in greater detail than it is possible to present here.

The important point is that CMS/RTI deliberately ignored the voice of the laboratory medicine profession. No more damning evidence can be laid at the CMS/RTI doorstep than the simple fact that the Laboratory "Technical Expert Panel" selected by CMS was never convened to meet in person and as a group for the purpose of providing CMS with detailed input into the design and implementation of the lab competitive bid demo.

Yes, there was at least one introductory meeting with all parties physically present. And yes, there were some conference calls. But several laboratory technical experts admit that their thoughts, ideas and concepts were never solicited by CMS and RTI. Rather, the meeting and conference calls were progress reports by CMS/RTI to the technical experts.

No Input From Lab Experts

By the way, some of the technical experts tell THE DARK REPORT that the last conference call organized by CMS was almost two years ago! Since the 2003 legislation calling for the competitive laboratory bidding demonstration project, CMS and its contractor, RTI, have repeatedly assured the laboratory community that it would have input and a role in helping to develop the competitive bidding demonstration project. Yet that has not happened.

By shutting out legitimate input and interaction with the laboratory industry, CMS didn't even swing at the ball! That's a called third strike, meaning CMS is out at the plate before the competitive bid demo is even ready to commence.

There's real irony in the fact that the Medicare program requires healthcare providers to listen to the voice of patients—yet its own officials seem to have intentionally ignored the voices of the key stakeholders in the San Diego MSA bidding demo site.

By failing to learn from the experience of these important stakeholders. CMS and RTI are charting a course that may make everyone unhappy with the outcome, including the Medicare program! TDR

Using a 1997 Bid Model In a 2007 Health Market

➤San Diego Demo Plan was created in 1997; Doesn't reflect current lab marketplace realities

➤➤CEO SUMMARY: It's been a long path from concept to implementation for a competitive bidding demonstration involving clinical lab services. It was in the mid-1980s when CMS commenced work on designing such a demonstration. In the 1990s, RTI International continued development of the concept and, in 1998, it published a paper on the plan it had developed for the laboratory competitive bidding demonstration project. This 1998 plan forms the basis for the upcoming 2008 demo pilot in the San Diego MSA.

IS MEDICARE PREPARING TO DUMP A VINTAGE-1987 CONCEPT onto San Diego's state-of-the-art 2007 healthcare system? Is the soon-to-be implemented Medicare Clinical Laboratory Services Competitive Demonstration Project based on a design that, given healthcare's evolution over the past 10 years, has the potential to trigger disruptions to beneficiary access and to the continuity of lab testing services for physicians?

THE DARK REPORT asks these two questions because the Medicare Clinical Laboratory Services Competitive Demonstration Project that was announced and described at the bidders' conference in San Diego, California on December 5, 2007, is essentially the same as the laboratory competitive bidding demonstration project that Medicare and its contractors first made public in 1997.

Thus, federal healthcare bureaucrats may be implementing a laboratory pricing concept that time and progress in the American healthcare system has rendered outmoded, even obsolete. The reluctance of the **Centers for Medicare & Medicaid Services** (CMS) and its contractor, **RTI International** (RTI), to engage the laboratory medicine profession and other healthcare stakeholders to rigorously rethink and update a bidding demonstration plan originated in 1997 is another serious objection to the impending implementation of the laboratory competitive bidding demonstration pilot for the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area).

➤Bid Idea Surfaced in 1987

In all the commentary and criticism directed at the pending Medicare Clinical Laboratory Services Competitive Demonstration Project, few have observed that the original design work for laboratory competitive bidding was launched in 1987! At that time, the **Health Care Financing Administration** (HCFA—now CMS) engaged outside contractors to develop a program of laboratory competitive bidding.

This work resulted in studies completed in 1987 and 1989 by **Abt & Associates** of Cambridge, Massachusetts, addressing the framework for a demonstration and evaluation of competitive

bidding as a method for purchasing clinical laboratory testing services.

HCFA continued this development work for another 10 years. During 1996-97, Research Triangle Institute (RTI) completed a contract with HCFA to produce a detailed plan for a laboratory competitive bidding demonstration project. RTI published the results of this work in the form of a paper titled "Medicare's Demonstration of Competitive Bidding for Clinical Laboratory Services: What It Means for Clinical Laboratories." This paper appeared in *Clinical Chemistry* (44:8, 1728-1734 [1998]). For laboratories involved in preparing bids, this would be a helpful document to review. It can be accessed at the Web site of the **American Association of Clinical Chemistry** (AACC). *(See sidebar at right.)*

During the 1990s, CMS (then HCFA) publicly declared its objective of conducting a demonstration project for the competitive bidding of clinical laboratory services. It had similar plans for other healthcare services, such as durable medical equipment (DME). However, for various reasons, prior to 2003, the laboratory bidding demonstration was never implemented.

Congress Acts On Lab Demo

In the legislative logrolling that produced the Medicare Modernization Act (MMA) of 2003, the statutory requirement for CMS to conduct a lab competitive bidding demonstration made it into the final law. This gave CMS the authorization to conduct its long-desired experiment with laboratory bidding.

In September 2004, CMS contracted with RTI (and its subcontractor **Palmetto GBA, LLC**) to assist CMS in the "design (Phase I: demonstration design, develop solicitation and bid process, claims processing plan, management), and operation (Phase II: operate bid sites of the demonstration)." John Kautter, Ph.D., of RTI was made director of the project and continues in that role today.

Not Much Has Changed To the Demo Plan in 10 Years

WILL MEDICARE PATIENTS, THEIR PHYSICIANS AND LABORATORIES in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) be subjected to a laboratory competitive bidding demonstration plan that has changed little since its creation in 1997?

To judge for yourself, three primary documents dating from 1998, 2005 and 2007 are readily accessible. PDFs of the original documents can be accessed via the Internet. These documents make it possible to compare how the design of the project has evolved from its 1997 form.

1997–RTI International (then Research Triangle Institute), under contract with the Healthcare Financing Administration (HCFA) produces a detailed plan for competitive bidding to set fees for Medicare Part B clinical laboratory services. It publishes a description of the project in *Clinical Chemistry* 44:8, 1728-1734 (1998). Access the document at: *http://www.clinchem.org/cgi/content/abstract/44/8/1728.*

2005–RTI presents its plans for the competitive bidding demonstration project mandated by the 2003 MMA legislation. The August 2005 presentation is titled: "Summary of the Medicare Clinical Laboratory Competitive Bidding Demonstration Draft Design. Access the powerpoint presentation at: *http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_Handout.pdf.*

2007–CMS and RTI officials distribute the full bidder's package for the San Diego MSA. Access these documents at: *http://www.cms.hhs.gov/center/clinical.asp.*

At this time, the 1997 plan for competitive bidding of clinical laboratory services was taken down from the shelf and dusted off. In the summer of 2005, RTI gave a public presentation describing the proposed form and implementation of the laboratory competitive bidding demonstration. It was substantially the same design as described

in the paper published in 1998. Further, the bidders' package and application distributed at the bidders' conference in San Diego contains requirements and structure that are relatively unchanged from both the 1998 paper and the 2005 presentation.

No Lab Input In Demo Design

During the three years since CMS executed the design and implementation contract with RTI, neither group has engaged the laboratory industry in a meaningful way for advice, input, and help in creating a form and structure for the laboratory competitive bidding demonstration project that will meet the two goals defined in the mission statement (lowering Part B pricing for lab testing and maintaining access and quality for Medicare beneficiaries). Yes, a Technical Expert Panel was named, but members of the panel note that they only had one meeting as a group, several years ago. *(See sidebar at right.)*

Turn back the clock to the mid-1990s, when the primary design work was done for the laboratory demonstration project that is now unfolding in the San Diego MSA. At that time, closed panel, gatekeeper-model HMOs held the largest enrollment of insured lives. There were three billion-dollar laboratory companies and many cities had a regional independent laboratory company.

Lots Of Changes In 10 Years

Fast forward to today's healthcare market. Restrictive HMO plans have almost disappeared in favor of PPO and POS plans, often in HDHP (high-deductible health plan) form. Other health insurance concepts, such as HSA (health savings accounts) are growing in enrollment.

There have been equally radical changes in the laboratory testing marketplace. Now two super-huge laboratory companies dominate nationally, having spent the past 10 years buying most of the regional independent lab companies that came to market. Another new phenomenon is the large and growing numbers of hospital laboratory outreach programs.

Technical Expert Panel Was to Advise CMS/RTI

AS ANNOUNCED SEVERAL YEARS AGO, the Technical Expert Panel (TEP) was "to operate during the design and startup of the operational phase" of the laboratory bidding demonstration project. Members tell THE DARK REPORT that they have only met once as a group and the last conference call as a group was almost two years ago. Here are the members named by CMS/RTI for the Technical Expert Panel:

- **ALFRED CHIPLIN, J.D.**—Managing Attorney for the Center for Medicare Advocacy, Inc., in Washington, DC.
- **CARLYN COLLINS, M.D., MPH**—Senior Laboratory Advisor for the Public Health Practice Office (PHPO) at the Centers for Disease Control and Prevention (CDC).
- **MARC GRODMAN, M.D.**—Chairman, President, & CEO, Bio-Reference Laboratories, Inc., Elmwood Park, NJ.
- **LEE HILBORNE, M.D., MPH**—Director of the Center for Patient Safety and Quality, University of California Los Angeles (UCLA) Healthcare.
- **DONNA MACMILLAN, MT (ASCP), MBA**—Director of Operations for the Department of Pathology at Massachusetts General Hospital (MGH).
- **JAMES ROBB, M.D.**—Medical Director at Integrated Regional Laboratories of Fort Lauderdale, FL.
- **BONITA WARNER**—National Vice President, Network Services for AmeriChoice Corporation.
- **RONALD WEISS, M.D., MBA**—Professor of Pathology, University of Utah School of Medicine, Salt Lake City, UT.

By proceeding with a competitive bidding demonstration plan developed for a mid-1990s healthcare market—and by not engaging the laboratory profession in updating this bidding model, CMS is less likely to be successful with the San Diego MSA pilot demonstration. TDR

Call to Action Is Needed For Lab Test Profession

Passive cooperation failed to engage CMS/RTI during development of competitive bidding demo

CEO SUMMARY: Is a laboratory test simply a commodity, like wheat or coal? Or is it a complex scientific service of unique value that delivers personalized results and clinical knowledge on behalf of millions of patients every day in the United States? The fundamental assumption of competitive bidding for clinical laboratory testing is that one lab's test result is equal to another. It is time for the laboratory medicine profession to come together and tell its story to the public and elected officials.

By Robert L. Michel

Is it necessary for Medicare officials to disrupt a smooth-running system of laboratory testing services in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) before learning the lesson that every pathologist, Ph.D., and medical technologist knows, that laboratory testing is a complex science and not a commodity product, to be treated like corn, soybeans, and iron ore?

Competitive bidding for laboratory testing is based on a basic premise: the test result from one lab is fully substitutable for the test result from another lab. Thus, Medicare, as a buyer, can get the lowest price—at comparable quality—by competitive bidding.

But there are greater stakes on the table than simply a competitive bidding demonstration pilot in the San Diego MSA. At the December 5 bidders' conference, toward the end of the day, officials from the **Centers for Medicare & Medicaid Services** (CMS) stated that the bids submitted on February 15 will function as a prototype to allow them to develop a new Part B laboratory services fee schedule for Congress.

This is major news for the laboratory industry and has gone unreported nationally until now. It exponentially magnifies the negative effects that are likely to result from the poorly-designed, overly-complex, and subjective San Diego MSA competitive bidding project.

Basis For National Lab Fees

It means that, even before the end of the three-year demonstration project, CMS intends to build a new national fee schedule for laboratory services using the bids submitted in what is recognized by the laboratory profession to be a poorly designed and flawed pilot demonstration project. Therefore, with the February 15 deadline looming for the acceptance of bids for the first pilot of the Medicare Clinical Laboratory Services Competitive Demonstration Project, the laboratory medicine profession in the United States has come to a crossroads.

It would be timely for the laboratory medicine profession to come together to

achieve multiple goals. Some obvious objectives would be: 1) to delay the February 15 bid submissions, especially since CMS has now publicly acknowledged it wants to use these bids to craft a new national fee schedule; 2) to cause a delay in the implementation of the San Diego MSA, specifically to allow the voices of patients, providers, and laboratory professionals to play a role in revising and reforming the form and shape of the competitive bidding demonstration to correct its flaws; 3) to effect a public education campaign that reaches the American public, particularly Medicare beneficiaries in the San Diego MSA. This campaign should also reach out to local and national media, as well as elected officials.

The best tool to achieve these goals is the truth. Accurate information, widely disseminated, has the power to energize natural allies in this effort to reform the competitive bidding project and fix the problems. I would like to respectfully submit several suggested "calls to action" which a unified laboratory profession could use to achieve these objectives.

➤Call to Action: White Paper/Position Paper on Lab Bidding Demonstration

Having cooperated fully with CMS/RTI as requested for three years—and having been ignored in virtually every aspect of the bidding design, bidding evaluation process, and implementation plan, it is morally right for the laboratory medicine profession to speak out...to go on record with a detailed position paper that identifies the gaps in healthcare care, patient services, and continuity of access that will occur for three years in the San Diego MSA.

To have maximum effect and credibility, this position paper must be produced and endorsed by a coalition of laboratory medicine professional groups that cross all specialty medical boundaries. The existing **Clinical Laboratory Coalition** makes a good critical mass for organizing this effort, and every laboratory medicine trade association, professional society, and lab vendor group should want to lend their name and endorsements to this effort.

The immediate goal is to produce a "White Paper" or position paper that is comprehensive and detailed. The White Paper must analyze and comment on all aspects of the Medicare Clinical Laboratory Services Competitive Demonstration Project. It must be blunt in its treatment of the proposed requirements, providing a detailed assessment of the flaws and oversights in the plan described by CMS/RTI.

➤Impact On Medicare Elderly

Further, this White Paper should provide a detailed discussion of how the demonstration project will affect these stakeholders: Medicare beneficiaries with a residence in a San Diego MSA zip code; physicians and other providers who treat Medicare patients in that area; and the impact of the bidding scheme on all classes of laboratories that provide lab testing and diagnostic consulting services.

Finally, the impact of this White Paper would be intensified if the laboratory medicine profession engaged an internationally respected business resource to study the announced plan for the competitive bidding demonstration project for the purpose of providing a detailed critique of the plan, along with recommendations for fixing its flaws and failings. Of course this takes money and time, but it brings immense credibility to the findings.

➤Call to Action: Public Education Effort, Involving Media, Patient Advocacy Groups, Disease Associations, Physician Groups

As this White Paper is ready for public release and distribution, the laboratory medicine alliance/coalition would benefit immensely from a major public education campaign. This campaign should target the media at the local, state, and national level. It should reach out to patient advocacy groups and disease associations. It

should also include communication with physician specialty associations, telling the laboratory medicine side of the story and asking for support and recognition by other medical specialty associations and societies.

Included in the White Paper/position paper document should be individual case studies of how laboratory medicine makes a difference, because of the diagnostic knowledge and expertise that helps physicians know the right test to order, and then the right thing to do with the lab tests results. Humanize how the power of laboratory medicine makes an incredible difference in the lives of patients every day.

Of course, the persuasive clinical value and economic leverage of lab medicine services needs to be outlined. The White Paper/position paper is the place to make both the financial case and the clinical case that laboratory medicine is a high quality clinical service, as well as one of the most cost-effective medical specialties in healthcare. It should not be treated as a commodity.

Call to Action: Educating Elected Officials

These educational materials can be delivered to elected officials and combined with personal meetings by lab medicine professionals to tell the full story. Officials and their staff advisors at city, county, state, and federal levels should be briefed. Such meetings with elected officials can be arranged to include patients, patient advocacy groups, and those disease associations that want to support a reform and revision to the current laboratory competitive bidding demonstration project.

Call to Action: Funding this Effort and Implementing the Campaign

Because of the looming February 15 date, there is a need for swift action. The laboratory medicine profession will require three resources to accomplish these calls to action: leadership, funding, and manpower.

Across the lab industry, there are plenty of leaders, but they need to come together and unite behind a single goal: reforming the competitive bidding demonstration project so that it can proceed without disrupting access to quality laboratory testing by Medicare beneficiaries, and their physicians, and without triggering erosion of laboratory services in the San Diego MSA.

It will take money to create and implement a public education campaign. Fastest sources of funding are likely to be industry vendors, such as the *in vitro* diagnostics (IVD) companies, certain lab industry associations, and the personal contributions of pathologists, lab executives, and others involved in laboratory medicine.

With leadership and funding in place, people are needed with the demonstrated skills and time to implement the public education campaign, to organize meetings with patient groups and elected officials, and contact local and national media. The public education campaign should have adequate funding to support these people in their work on behalf of the laboratory profession.

Positive Reforms As A Goal

Most of the diverse interests in the laboratory medicine profession converge on the goal of positive reforms to the national Medicare Part B laboratory fee schedule. For that reason, assembling an ample war chest to fund a White Paper/position paper, in tandem with a professionally-executed campaign of public education, can be the type of "out of the box" thinking needed to get the right action on this important subject.

These suggestions are respectfully submitted as a starting point to craft an effective response to the new implications of the Medicare Laboratory Competitive Bidding Demonstration Project soon to unfold in the San Diego MSA. TDR

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Speculating On How Labs Might Respond to Demo

➤Consequences of the bidding demonstration may swiftly alter national Medicare Part B prices

➤➤CEO SUMMARY: Statements and actions by CMS officials responsible for the laboratory competitive bidding demonstration project reveal the likelihood that they are using it as a Trojan Horse. While talking about implementation of a three-year demonstration project in the San Diego MSA, CMS dropped hints that it will use the bids submitted on February 15 as a prototype for a new national Medicare Part B schedule for implementation as early as next fall, at the start of fiscal year 2009.

By Robert L. Michel

FEBRUARY 15, 2008, IS SHAPING UP to be a seminal day in the long-term clinical and financial fortunes of the laboratory medicine profession.

On that date, a handful of labs, probably not more than 10 or 12, are expected to submit bids and applications to be Medicare Part B laboratory test providers for the three-year term of the Medicare Laboratory Competitive Bidding Demonstration pilot site in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area).

➤Setting Events In Motion

Once those bids are submitted, I predict a series of events will be set in motion that will have ongoing consequences for the laboratory profession—not only those serving Medicare beneficiaries in the San Diego MSA, but for labs all across the United States. That's because officials at the **Centers for Medicare & Medicaid Services** (CMS) will use the bids submitted by these laboratories on February 15 as a "prototype" (one CMS official's characterization) for a national Medicare Part B laboratory price schedule. This price schedule could be used to influence Congressional funding as early as fiscal year 2009.

Thus, what is in play on February 15 is not only access to some 209,000 Medicare fee-for-service (FFS) beneficiaries, of which as many as 80% are already served by **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**. Rather, the other objective on February 15 is Medicare's wish to have laboratories provide it with a range of bids that indicate the rock-bottom prices labs will accept as payment for Part B lab tests (in the San Diego MSA). Medicare will then turn around and use this information as a prototype to allow it to establish a new national Part B fee schedule it can implement as early as next October!

Many would argue that it is irresponsible for CMS to proceed in this manner. What a handful of labs submit as bids (in a poorly-designed and highly-flawed auction) to serve patients in San Diego is not a relevant pricing sample upon which to base a new national Part B fee schedule. Yet, there are plenty of indications that CMS intends to use the San Diego bids for

exactly that purpose. Such arbitrary slashing of fee-for-service reimbursement for Medicare Part B laboratory testing would be a short-sighted action with major long term consequences.

Short-Term Focus

However, it must be recognized that politicians and bureaucrats are not good at long-term planning. Their focus is on the short term and the next budget/election cycle. Case in point is the huge Social Security funding gap in coming years. Congress spends the money today that baby boomers will need in downstream retirement years. Yet neither political party has the will to cease spending incoming Social Security payments on current government programs.

Short-term thinking is one reason why CMS officials have turned the competitive bidding demonstration into a Trojan Horse. Nominally, CMS tells the public that this is the first of two three-year pilot sites. In reality, CMS is ready to harvest the San Diego MSA bids and use them as the prototype for a new national Part B laboratory fee schedule, as early as next October.

Local Bid Used Nationally

Thus, there a number of reasons one could use to argue that an important component for the future health and vitality of the laboratory medicine profession in the United States rests on a small handful of labs eligible to bid on February 15. Their decisions to participate, and their strategies for bidding, have consequences far out of proportion to the immediate challenge of preserving their right to serve some 209,000 Medicare elderly in San Diego.

That makes it interesting to speculate on the range of bidding strategies that individual labs might consider as February 15 approaches. First, assume that, in fact, CMS officials are highly interested to get access to these bids—more for use in a national Part B lab price schedule rewrite, than for the San Diego pilot—then one response is to not give them bids.

This could drive a strategy by the laboratory profession at large to delay the February 15 bid submission until the widely-recognized flaws in the design of the lab competitive bidding demonstration plan are fixed. With delay in the February 15 bid submission date as the goal, labs currently serving San Diego would need assistance from state and national laboratory associations and organizations.

These respected and credible laboratory groups would need to issue public statements in support of a delay. There should be reasons why a delay is justified and a list of identified problems that need to be fixed before the demonstration proceeds to the bidding submission stage. The White Paper/position paper concept I discussed on pages 25-27 would help in this effort.

Seeking A Court Injunction

Another approach is for a party to the laboratory demonstration project to go to court and file for an injunction to delay the February 15 bid submission date until the issues that concern labs in San Diego can be adjudicated and resolved. It is wistful thinking, but an ideal candidate to seek relief through the courts would be one of the hospitals or health systems in San Diego that operates a laboratory outreach program.

After all, a hospital laboratory outreach program is the perfect example of integrated patient care. The same laboratory provides inpatient, outpatient, and outreach testing services and the patient's physicians have full access to this complete record of laboratory testing. Because the competitive bidding demonstration threatens to prevent the hospital lab from providing Part B lab tests to the same patient it is testing under Part A, the San Diego press is likely to pick up on this negative aspect of the bidding demo's design. Plus, media coverage would also alert Medicary beneficiaries about how they are being made guinea pigs in an effort to shave a few pennies from the cost of Medicare Part B lab testing.

Funding for a legal strategy can come from some type of war chest effort organ-

ized by national laboratory leaders. There are enough lawyers who specialize in laboratory and diagnostic testing law to help create a lawful funding entity to provide for the legal costs of going to court and seeking an injunction. Lab industry vendors can also step up and help generate funds needed to mount and sustain a legal challenge to the laboratory competitive bidding demonstration in its current form. This is doable. Further, if a San Diego-based laboratory or hospital knew that it would have help with the legal expenses and the support of the national laboratory profession, that increases the odds that a willing plaintiff for such a legal action could be found.

The "No Bid" Strategy

Independent of a legal challenge, would any laboratory serving San Diego adopt a strategy of not bidding? That is an interesting question. For **Internist Laboratory** in Oceanside, and for the lab outreach programs of **Sharp Health Care**, **Scripps Health**, and **Alvarado Hospital**, among others, that is not likely to be a welcome option. Internist Labs needs access to Medicare patients (65% of its patient mix). For the hospital labs, their mission is to serve their parent hospital and treat the patient as he/she moves from hospital to clinic and doctor's office. Being excluded from serving Medicare patients would be very disruptive to such an integrated health delivery model.

Similarly, for the two blood brothers, not bidding is not a rational strategy. Together, they hold an estimated 80% of the Medicare Part B lab market in the San Diego MSA, The business represents about $17 million of the $21 million Medicare says it paid out in 2006 in San Diego. In revenue dollars, it's not much for either lab company. But both labs have a marketing strategy based on being a contract provider for as many health plans as possible. Thus, if one lab company were to lose the ability to serve Medicare Part B beneficiaries, its competitor would use that as a wedge to win new clients.

Viewed from these perspectives, no lab currently serving the San Diego MSA is likely to adopt a "no bid" strategy. Therefore, if it was in the best interest of the laboratory profession to avoid submitting bids on February 15 and/or until recognized flaws and problems with the competitive bidding demonstration are resolved, then the legal strategy of pursuing an injunction seems to be most feasible.

May Be Wide Range Of Bids

Assuming, then, that all qualified lab players serving San Diego plan to submit bids, are there any price/discount strategies that can be anticipated? Probably not, because of several economic factors. Each laboratory has a cost structure influenced by volume, internal test menu, and instrumentation/automation. Add direct costs such as patient service centers, courier/logistics, IT connections to client offices, and each lab's cost per test will vary widely. Further, San Diego's aggressive managed care market may mean that all labs serving that community are already working on thin margins and don't have much ground to give in bidding for the demonstration project.

Is Court A Viable Strategy?

The speculation presented on these pages shows that it is unlikely that the laboratory profession, either locally in Southern California or with its national leadership, is likely to derail the scheduled progression of events, short of going to court and seeking an injunction to delay implementation.

Opting for legal action seems a justifiable approach, particularly because CMS and RTI have kept the laboratory profession at arm's length during the three-year design phase of this competitive bidding demonstration project. However, it would require that the entire laboratory profession come together in an unprecedented way and take action in the few weeks remaining before February 15. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's late-breaking news affecting new federal rules for the anti-markup provisions scheduled to become effective on January 1, 2008. Just days ago, the federal **Centers for Medicare & Medicaid Services** (CMS) issued a final rule that generally delays, until January 1, 2009, some of the anti-markup provisions in the 2008 Medicare physician fee schedule which were to take effect on January 1, 2008. However, Attorney Rick Hindmand of **McDonald Hopkins** observes that pathologists will want to note this fact: CMS specifically identified anatomic pathology diagnostic testing arrangements as its "core concern." Therefore, CMS did not delay the rule with respect to anatomic pathology diagnostic testing services furnished in a centralized building that does not qualify as the "same building" under the Stark regulations.

MORE ON: Anti-Markup

CMS said it would delay until next year the applicability of the anti-markup provisions in the 2008 Medicare physician fee schedule—except for the technical component of purchased diagnostic tests and any anatomic pathology diagnostic testing services furnished in space a physician group uses as: 1) a "centralized building" for purposes of complying with the physician self-referral rules; and, 2) does not qualify as a "same building." The rule will be published in the *Federal Register* on January 3, 2008. It is notable that federal healthcare regulators are making this distinction. It indicates that interest remains keen to curb certain arrangements that allow specialist physicians to mark up anatomic pathology services.

ALVERNO GROWS WITH EIGHT MORE HOSPITAL LABS

Earlier in December, **Resurrection Health Care** of Chicago, Illinois, entered into an agreement to become an equal partner in the **Alverno Clinical Laboratories** venture, based in Gary, Indiana. Existing partners are the **Sisters of St. Francis Health Services** and **Provena Health**. Alverno CEO Cheryl Vance will be integrating the laboratory services at Resurrection's eight hospitals with Alverno's regional laboratory organization, including a central laboratory in Gary, Indiana, and 18 hospitals in Indiana and Illinois. The combined network of 26 hospital laboratories will become one of the nation's largest integrated laboratory operations, both in size and geography served.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, January 21, 2008.