3 Giralda Farms
Madison, New Jersey 07940
QuestDiagnostics.com

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By Email

Mr. John Mendoza
Acting Chief of Fee for Service and Rates Development Division
Post Office Box 997413 M.S. 4612
Sacramento, CA 95899-7413
labcomments@dhcs.ca.gov
john.mendoza@dhcs.ca.gov.

Re: Quest Diagnostics Incorporated's Additional Comments in Connection with Clinical Laboratory Rate Setting Stakeholder Meeting on August 24, 2012

Dear Mr. Mendoza:

As you know, on August 20, 2012, Quest Diagnostics Incorporated submitted a letter, as part of the stakeholder input process recently mandated by AB1494, to set forth its views concerning (a) the data that DHCS should require labs to submit under the statute and (b) how DHCS should use that data in the new rate setting methodology that it is required to develop under the statute. I am writing to supplement those comments with additional details concerning the nature and format of the data that we believe DHCS should (and should not) require to be reported by California labs.

Further Details of Recommended Reporting

We proposed in our August 20th letter that DHCS should require each lab to submit the top five fee schedules, by CPT Code, that it has negotiated with fee-for-service payors (*i.e.*,

insurance carriers) in California,[1] that are in effect on a specified date during the reporting period.[2] We also recommended that the volume of tests reimbursed by the insurer under each such fee schedule be reported, on a CPT code basis, so that DHCS can perform weighting or averaging as part of its rate setting analysis (and can therefore, for example, eliminate outliers). Finally, we stated that it should be possible to develop a spreadsheet for such reporting so that DHCS can appropriately analyze the reported insurer CPT-code specific fee schedule data during DHCS's new rate-setting process, and we also stated that Quest Diagnostics would be willing to work with DHCS on the development of such a spreadsheet.

To assist in the development of a reporting spreadsheet, we have enclosed a template (in Excel spreadsheet form) that we recommend to DHCS for distribution to each California lab covered by the statute. It is designed to capture, in a convenient format, the key insurer fee schedule and utilization information that we think DHCS should gather for the top five contracted insurer fee schedules (as described above), so that DHCS can most effectively and fairly develop a CPT-code specific Medi-Cal fee schedule of its own. Each reporting lab would be required to complete and submit five of these templates, one for each of its top five contracted insurer fee schedules (as described above). The spreadsheet calls for the information set forth in the table on the next page.

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1 In order to preserve confidentiality (and in light of contractual confidentiality provisions), we propose that the identity of each insurer whose fee schedule is being reported be masked. Instead, each lab should keep a confidential record of the reported fee schedules and should certify that it has determined such schedules to be the largest five fee schedules for the relevant period.

2 To be clear, the "top five" fee schedules should be those under which the lab has been reimbursed for the highest number of tests ordered in California (measured by CPT code), in the aggregate. That is, the top five fee schedules should be determined by aggregate test *volume* (measured by CPT code) for tests ordered in California, not by aggregate reimbursement *dollars*. Furthermore, since the statute requires data reporting from the prior year, we recommend that the specified reporting date be December 31 of each year.

Confidential Information Concerning Contracted Fee Schedule # 1
From XYZ Clinical Laboratory

A	B	C	D	E
CPT Code	CPT Description	Number of CPTs Billed Under this Fee Schedule for the Prior Calendar Year as of 12/31	Insurer's Fee Schedule Rate as of 12/31 of Prior Calendar Year	Any volume-based adjustments? (Yes or No). If yes, provide detail in text box below[3]
1234	ABC	50,000	$5	No
2345	BCD	60,000	$20	No
3456	EFG	20	$4	No
4567	HIJ	20,000	$10	No
5678	KLM	10,000	$30	No

The information described in the spreadsheet should be supplied (on a confidential basis) for each and every CPT code from the applicable insurer fee schedule that pertains to clinical laboratory services. The test volume information (column C) should be used to eliminate outliers (such as CPT EFG in the hypothetical table), and can also be used by DHCS to develop weighted average fee amounts across multiple insurers and multiple labs. The fee schedule for each CPT code should be the insurer's fee schedule in effect as of December 31 of the prior calendar year. Column E would require the lab to disclose, for each of the reported five fee schedules, whether the contract at issue includes any volume-based adjustments, and if so the lab would be required to describe such adjustment(s) it in a box on the spreadsheet in sufficient detail to enable DHCS to determine if the adjustment would apply to the number or dollar value of the lab's aggregate CPTs that are reimbursed by Medi-Cal.

Quest Diagnostics would be happy to work together with DHCS to further refine this reporting template, should DHCS have any technical issues or questions.

[3] The text box would include the following instruction: If yes in Column E, separately describe the contractual volume-based adjustment in sufficient detail to enable DHCS to determine if it would apply to the number or dollar value of your lab's aggregate CPTs that are reimbursed by Medi-Cal. For example "The contract allows the insurer to make an adjustment of X to its Fee Schedule if its aggregate reimbursements to XYZ Laboratory exceed $10,000,000 in a calendar year."

Data that DHCS Should Not Require to Be Reported

As we stated in our August 20th letter, neither "capitated" rates nor "client" rates offer meaningful guidance on the amount that Medi-Cal's fee-for-service program should establish for each CPT code in its Medi-Cal fee schedule. We do not believe that AB1494 requires the reporting of any such rates, and we strongly recommend that DHCS limit the data it seeks from each lab to the top five contracted insurer fee schedules, as described above.[4] As an initial matter, DHCS will receive a very substantial amount of data if each clinical laboratory in California that makes Medi-Cal claims is required to report just the data we have recommended. In fact, DHCS will quickly be inundated with irrelevant data if it requires labs to report capitated rates or client data as well. In addition, such data should not be required for the specific reasons set forth below.

A. **Capitated Arrangements Are Fundamentally Different from Fee-for-Service Billing and Cannot Be Used to Create Medi-Cal Fee-for-Service Benchmarks for Lab Tests.**

Medi-Cal is increasingly delegating its beneficiaries to MCOs under capitated arrangements. Clinical labs that perform testing services for such "delegated" Medi-Cal patients are already being compensated for those testing services under capitated arrangements. This "capitated" part of the Medi-Cal program, however, has nothing to do with what reimbursement rates Medi-Cal sets for the fee-for-service part of the Medi-Cal program, which is what is at issue in this stakeholder process. Similarly, the labs' capitated business arrangements should have nothing to do with the determination of Medi-Cal's fee-for-service reimbursement rates. It's simply apples and oranges, as further explained below.

In the managed care context, Quest Diagnostics and other laboratories sometimes contract to provide laboratory services on a "capitated" basis. Under these arrangements, charges are not made on a test-by-test, or "fee-for-service" basis. Instead, the lab is paid a set "per-member-per-month" amount (that is, a flat rate) for patients covered by the capitated arrangement, regardless of the number or type of lab tests actually performed for those patients each month.

Capitated arrangements, as applied to lab tests, can arise in a number of ways. For example, a private-payor like Aetna (or a government payor like Medi-Cal) may contract with a Managed Care Organization ("MCO") to pay the MCO (or a downstream entity), on a "per-member-per-month" basis, for *all* medical services (not just lab tests) provided to the payor's beneficiaries. The MCO, in turn, often will subcontract with one or more downstream entities to provide services to some or all of the MCO's "covered lives." The arrangements with such downstream entities are very frequently also on a capitated basis.

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[4] We recognize that the statute also requires that the rates of certain other Medicaid programs be reported, which is addressed in our prior letter.

Under these capitated arrangements, the "per-member-per-month" amount is paid each month regardless of whether any particular beneficiary receives no medical care, a substantial amount of medical care, or anything in between. In these arrangements, the payor, the MCO and any downstream entities are all at risk with respect to the overall level of services performed. If utilization is lower than projected, the payor incurs more expense than it would like. Similarly, if utilization is higher than projected, the MCO and/or the downstream entities are required to provide those services with no additional fees and are subject to the resulting increased costs. Risk allocation will vary among capitated deals, depending on, among other things, the demographics of the covered beneficiaries involved (sometimes referred to as "covered lives"). For example, a MCO with many Medicare members (primarily elderly persons who tend to need more extensive medical services) could have a higher capitated payment rate than the amount that could be negotiated by a private MCO having a younger, healthier member population needing fewer medical services.

There are significant differences between (1) a simple fee-for-service arrangement that applies when a lab performs a lab test for a Medi-Cal patient under its fee-for-service program and then simply bills Medi-Cal, and (2) a complex, multi-layered capitated deal that involves per-member-per month payments to the lab as described above. Capitated deals -- unlike fee-for-service arrangements -- involve important elements of utilization management and negotiated risk allocation. These elements make valid comparisons of capitated deals with the Medi-Cal fee-for-service model impossible for at least two reasons. First, the per-member-per-month fee for lab services under any capitated deal depends on, among other things, a managed patient population's testing history. With capitated arrangements, the utilization of lab testing is proactively managed, which is not the case with Medi-Cal fee-for-service testing. Therefore, on average, the per-patient utilization is controlled under capitated arrangements in a way that Medi-Cal fee-for-service testing is not, making them non-comparable. Second, each capitated fee level is negotiated before either side knows for sure what overall testing level will be provided to the relevant population, and for what tests. So even if the amount of revenue received by a lab for capitated covered lives from a particular provider is divided after-the-fact for a given period by the number of tests performed, the average cost per test for each period would likely vary widely. And there will be wide variations in average after-the-fact costs per tests between and among the entities that have negotiated capitated deals, depending on a host of factors including patient population and the actual risk management performance of the entities involved. Any kind of after-the-fact analysis of average testing costs in a capitated arrangement removes the critical before-the-fact elements of utilization management expectations and risk allocation -- the central features of a capitated deal.

Furthermore, and most significantly here, even if we could develop some meaningful way to determine which capitated deals should be used as guidelines for Medi-Cal and how they translate on an after-the-fact basis into comparable costs for testing on an overall basis (which cannot be done), there would still be no way to use that data to determine what the Medi-Cal rate should be for any *particular test or CPT Code.* For example, if it turned out that there were 500 different types of tests performed on the covered lives in a particular capitated pool in a given month, each with its own "patient list" price of between $2 and $100, and the average price per test to the pool in a given month turned out (after- the- fact) to be $20, how would we use that

data to determine what the price for any *particular type of test or CPT Code* should be? The price for any given test or type of test is entirely irrelevant under a capitated deal, where the lab is paid on a per-member-per month basis each month regardless of the number or type of tests administered. So how could any kind of after-the-fact average cost per test data possibly be used to help set Medi-Cal rates for any particular test or CPT Code in a way that isn't completely arbitrary? The answer is that it could not. Simply stated, data on per-member-per-month capitated rates provides absolutely no guidance on what the CPT-code reimbursement rate should be for any specific CPT code.

2. Reporting of Charges to "Clients," such as Hospitals, Cannot be Required under the Statute and, in Any Event, Would Not Provide a Meaningful Benchmark for Setting the Medi-Cal Fee Schedule.

Clinical laboratories such as Quest Diagnostics often contract directly with clients, such as physicians or hospitals, to provide laboratory services. As explained in our August 20th letter, "clients" are not "payors," as those terms are used in the health care industry. Because AB1494 requires the reporting only of "payor" data, the reporting of client rates is not required by the statute. Thus, DHCS is simply not authorized by the statute to seek or obtain client pricing data.

"Payors," as that term is used in the health care industry, are third party insurers (like Aetna and Medi-Cal) that provide reimbursements to providers like Quest Diagnostics for providing services to their covered patients. "Clients," on the other hand, are entities like hospitals and clinics that contract with labs for their services, and usually pay them on a consolidated monthly basis, and may then obtain reimbursement themselves from a third-party payor.

By suspending Section 51501 and limiting data reporting to "payors," it is clear that the legislature has decided to move away from the complex "client" price tracking and reporting regime that had developed under Section 51501. Under that regime, DHCS, labs and the courts had to make difficult decisions about whether multiple kinds of client pricing arrangements (such as contracts with FQHC clinics, FQHC look-alikes, physician offices of all sizes and hospitals) for thousands of individual clients should be deemed "comparable circumstances" to those applicable to Medi-Cal. As we observed in our August 20th letter, a significant goal of AB1494 was to get away from the kind of broad, complex and burdensome reporting obligations and uncertainty that beset the 51501 regime, not to re-impose them.

We understand from comments made during the stakeholder process that some consideration may be given about whether DHCS should require labs to report one kind of "client" pricing data, namely data concerning lab pricing to hospitals. Again, we believe that the legislature clearly chose in AB1494 to require labs to report only "payor" data, and not any kind of "client" pricing data, which should put an end to this alternative. Nevertheless, below we provide some additional reasons why hospital pricing data does not provide an appropriate benchmark for setting Medi-Cal fee-for-service reimbursement rates.

Fundamentally, the circumstances of "client" arrangements, such as hospital contracts, are materially different from those that apply when a lab performs tests for a Medi-Cal patient outside of the client (*e.g.* hospital) setting and seeks reimbursement directly from Medi-Cal. Due to these differences, discussed below, labs are generally able to charge hospitals less, on a fee-for-service basis, than the reimbursements they receive from Medi-Cal and other fee-for-service third-party payors. The key differences between the circumstances surrounding hospital lab testing and billing and non-hospital Medi-Cal (and other insurer) patient testing and billing include the following:

a. When Medi-Cal patients are tested outside of the hospital setting, labs must typically bill Medi-Cal directly on a patient-by-patient basis. In contrast, labs do not directly bill patients who obtain lab services at a hospital, but, rather, they bill the hospital in one monthly invoice. That is, labs do not bill hospitals on a patient-by-patient basis, but, rather, they bill the hospital in a single monthly invoice for lab tests performed for all of the hospital's patients during the billing cycle.[5] This requires substantially less time, labor and expense on the part of the laboratory than does billing Medi-Cal separately on a patient-by-patient basis.

b. Service costs for lab testing in the hospital setting are lower than in the non-hospital setting as well. For example, specimen collection and processing (which are significant expenses for most non-hospital testing) are often performed by the hospital, and not by labs like Quest Diagnostics. Thus, in the typical situation, no laboratory Patient Service Center network is necessary for hospital testing. In the hospital context the laboratory does not need to supply the labor to process, create orders, or transfer or pack specimens for transport. Instead, the laboratory typically receives a split of a specimen from a collection performed by the hospital and, therefore, no collection materials have to be supplied by the lab.

c. In the hospital context there is often superior systems connectivity, in that most hospitals are bi-directionally interfaced to major labs such as Quest Diagnostics. This means that in the hospital setting, rather than a Quest employee having to enter the orders into the Quest Diagnostics Laboratory Information System manually, the orders are accepted into the Quest system electronically, directly from the hospital. This results in significant savings for Quest on labor (and also reduces ordering errors). Similarly, the reporting of lab results from Quest to the hospital is an automatic process rather than a manual one -- which also results in savings to Quest as compared with other arrangements.

d. Finally, and quite significantly, payments by hospitals are more prompt, the realization rate is significantly higher, and there are far fewer write-offs than when Medi-Cal or other third-party payors are billed directly for lab tests. Hospitals typically pay 100% of the fee schedule under which they are billed with virtually no reductions; there are no denials or disallowances. In contrast, the net realization on lab testing for regular Medi-Cal claims (after denials and disallowances) ends up being only about 75% of Medi-Cal's published lab test fee schedule on average. Thus, even if *none* of the other differentiating factors concerning hospitals

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[5] This is true for most non-hospital "client" billing as well.

discussed above were present, the Medi-Cal lab test fee schedule would still have to be set at significantly higher levels than a typical hospital fee schedule in order for Quest Diagnostics to achieve the same net realization.

For all of these reasons, hospital fee schedules for lab testing do not provide an appropriate benchmark for DHCS to use in setting the Medi-Cal fee schedule going forward. Thus, in addition to the fact that the statute does not authorize DHCS to require the reporting of client data (such as hospital fee schedules), it should not be required because – unlike major third-party payor data -- it does not provide a meaningful benchmark.

We hope that this letter provides some additional insights in connection with the stakeholder process. Quest Diagnostics stands ready to continue to participate in the process as it moves forward over the coming months.

Sincerely,

Jean-Marc Halbout
Quest Diagnostics
West Region Vice President

Cc: Edelstein Gilbert Robson & Smith