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November 14, 2012

By Email

Mr. John Mendoza
Acting Chief of Fee for Service and Rates Development Division
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Sacramento, CA 95899-7413
labcomments@dhcs.ca.gov
john.mendoza@dhcs.ca.gov.

Re: Quest Diagnostics Incorporated's Stakeholder Comments on DHCS's October 31, 2012 Proposed Data Submission Requirements for Clinical Laboratories

Dear Mr. Mendoza:

As you know, on August 20, 2012 and September 5, 2012, Quest Diagnostics Incorporated submitted letters, 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 DHCS is required to develop under the statute. For your convenience, those letters are attached hereto as Exhibits A and B. As stated at the recent public stakeholder meetings, the Quest Diagnostics' data submission proposals described in those letters were generally supported by the California Clinical Laboratory Association ("CCLA"), whose members include large and small labs throughout the state, and by Laboratory Corporation of America ("LabCorp"), the second-largest lab in California.

Unfortunately, DHCS's preliminary data submission proposal of October 31, 2012 completely disregarded the recommendations of Quest Diagnostics, CCLA and virtually all of the stakeholders who submitted written comments. As a result, the Department's proposal seeks too little of the right data and too much of the wrong data. Specifically, DHCS fails to seek certain data (such as volume/utilization data) that it will need to develop a Medi-Cal fee-for-service reimbursement schedule that will accomplish the Legislature's stated objective -- that Medi-Cal's fee-for-service rates be "comparable" to the fee-for-service payment amounts set by other "payors" in a way that is "in compliance with state and federal law." More significantly, DHCS's preliminary proposal seeks far too much data, in that it (a) seeks a volume of data that is

so huge that the industry simply cannot comply and, if it could, DHCS would be buried with extraneous data, (b) seeks several specific data elements that labs do not routinely calculate and/or cannot provide, and (c) seeks a number of data elements that are irrelevant to the development of a Medi-Cal fee-for-service reimbursement rate schedule that is comparable to other payors' schedules. Moreover, DHCS's proposal seeks some data elements that DHCS is not authorized to seek under AB1494. We strongly urge the Department to withdraw its preliminary proposal and to adopt, instead, the detailed data submission proposal previously made in writing by Quest Diagnostics, for the reasons set forth in our prior letters, as well as for the reasons stated at the August 24th and November 5th stakeholder meetings and the additional reasons set forth below.

Further Clarification Concerning the Quest Diagnostics Proposal

We proposed in our August 20, 2012 and September 5, 2012 letters that DHCS should require each lab to submit its top five fee schedules, by CPT Code, that it has negotiated with fee-for-service payors (*i.e.*, private insurance carriers) in California,[1] that are in effect on a specified date during the reporting period.[2] When referring to an insurer's contracted "fee schedule," we mean the insurer's reimbursement rate schedule that applies for each CPT code they cover. 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 proposed a straightforward template (on an Excel spreadsheet) for the reporting of the data, which would allow DHCS to collect all of the data it needs to set a competitive Medi-Cal fee-for-service CPT reimbursement schedule without imposing an excessive burden on the reporting labs. Quest Diagnostics continues to believe that its prior proposal should be adopted by DHCS.

In response to questions raised at the last stakeholder meeting, we want to make several clarifying points about our proposal.

First, the contracted third-party payor fee-for-service rate schedules we are saying should be reported are *not* the same as a lab's own "patient list" or "client list" fee schedules. Labs generally have two (and only two) "list price" fee schedules for their own tests. Most labs *bill* fee-for-service third-party payors at *the lab's* "patient list" fee schedule (with exceptions for

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1 In order to preserve confidentiality (and in light of contractual confidentiality provisions), we proposed that the identity of each insurer whose fee schedule is being reported be masked. Instead, each lab should be required to 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, we proposed that 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*.

some CPT codes in some instances). The lab's "patient list" price for a given CPT code is typically higher (sometimes by a significant amount) than the contracted third-party-payor's fee-for-service reimbursement rate for that same CPT code. The lower, contracted third-party payor reimbursement rate schedules that are negotiated with the major fee-for-service payors on a CPT-code basis (which vary payor-by-payor, sometimes widely for a particular CPT code) are what Quest Diagnostics is proposing should be provided to Medi-Cal under AB1494. In the vast majority of cases, the rate for each CPT code on that contracted third-party payor's reimbursement rate schedule is the rate that that payor ends up paying the lab for that CPT code (not counting denials and disallowances, for which all third-party payors, including Medi-Cal, have rules that apply regardless of the fee schedule amounts).[3] In some (atypical) cases, a lab may agree to a contractual volume discount with a third-party payor that could lower the ultimate reimbursement amount paid by the payor -- but the Quest Diagnostics data reporting proposal accounts for this by requiring a detailed disclosure of any such deals with the payors whose reimbursement rate schedules are being reported, so that DHCS can take any such deals into account when setting the Medi-Cal fee-for-service rate schedule.

Second, as previously explained, we think it is important that DHCS request volume (utilization) data on a CPT-code-specific basis for each CPT code on the five top payor fee schedules being reported – which is a data element that DHCS's preliminary proposal omits. As previously explained, such volume data is needed by DHCS to eliminate outliers, to calculate weighted averages across labs or payors, and/or to do various other statistical analyses of CPT-code specific payor rate amounts that may be deemed relevant by DHCS once all of the data is collected.

Third, our proposal is that one Medi-Cal fee-for-service fee schedule (for all lab CPT codes) should be set by DHCS for the fee-for-service part of the Medi-Cal program for the entire state of California. Therefore, we did not propose the submission of data about where tests were performed or billed, or any other geographic information. We believe that multiple schedules

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[3] It is important to note that the denial and disallowance rules of a third-party payor have nothing to do with that payor's CPT-code specific fee schedule, just as Medi-Cal's denial and disallowance and rules (which are among the most aggressive of all payors) have nothing to do with Medi-Cal's fee schedule. Since the goal of the AB1494 data gathering process is to allow Medi-Cal to establish its fee-for-service *fee schedule* (and not its denial/disallowance rules), there is no reason to gather data on private third-party payor denial and disallowance rules. Comparing a pre-denial/disallowance fee schedule (which Medi-Cal is charged with developing) to a post denial/disallowance net payment amount from other payors would be comparing apples and oranges. Moreover, denial/disallowance rules are quite complex and vary by payor. And, even more significantly, in many cases labs do not reconcile third-party payor denials and disallowances at the CPT code level -- they are instead simply reconciled at the total payment level. Thus, in many cases it would be impossible as a practical matter to provide data that would show how much less the lab was paid by a given payor for a given CPT code due to the payor's denial/disallowance rules.

based on geography will simply introduce unnecessary complication to an already complicated process.[4]

Specific Objections to DHCS's Preliminary Proposal

1. DHCS's Proposal Seeks a Huge Amount of Data that Would Impose a Crippling Burden Both on Major Labs Like Quest Diagnostics and on DHCS

DHCS states in its written proposal that it "seeks to obtain a wide range of data ... as we have not yet developed the specifics of the rate methodology [and] want to gather as much information as possible to ensure that lack of data does not prevent us from developing a sound methodology." At the recent stakeholder meeting, DHCS officials further clarified that it is DHCS's intention is to seek the approximately 20 listed data elements in its proposal for each CPT code for *every test* performed by each California lab during 2011. The sheer volume of this data would place an impossible burden both on the reporting labs to provide it, and on DHCS to digest it.

During the year 2011, Quest Diagnostics performed and billed more than 78 million tests in its California labs. Although we have not been able quickly to determine the number of CPT codes associated with those 78 million tests, because many common tests have more than one CPT code a conservative estimate is that Quest Diagnostics billed for tests with more than 100 million associated CPT codes in 2011. Thus, the DHCS data submission proposal (as DHCS explained it at the last meeting) would require Quest Diagnostics to report (in some cases after manual investigation or calculation) some twenty data points for over 100 million CPT codes -- or *over two billion data points.* This is obviously an enormously large amount of data to report and, both alone and when combined with the data that would be reported by all other California labs, would be an impossibly large amount of data for DHCS to process.

Moreover, a number of the specific data points in DHCS's proposal would be impossible or extremely burdensome for Quest Diagnostics to provide (in addition to being unnecessary and/or not authorized by AB1494, as explained below). In particular:

- Quest Diagnostics does not track the cost of testing by CPT code. There are many ways to calculate cost (and they can yield very different results), and requiring Quest to attempt to do so on a CPT-code specific level for each test would not only generate many methodological issues but would be so burdensome as to be impossible.

- It would be quite burdensome for Quest Diagnostics to report where each patient sample was taken, because that information is not included in the Quest Diagnostics billing systems.[5]

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[4] We would have no objection if, for ease of reference, each lab is required to include in its data report all of the California NPI numbers that the lab, including any of its affiliated entities, uses to *bill* Medi-Cal, along with the addresses of those labs.

[5] Also, contrary to the implication in some of the proposed requests for geographical information, "payors," which are typically insurance companies, are not the same as

- As noted above, in many cases Quest Diagnostics does not track the net amount realized (after denials and disallowances) on a CPT code-specific basis, and trying to do so in such cases would therefore involve a manual process that would require multiple assumptions and would be impossibly burdensome.

- In addition to being irrelevant to Medi-Cal's establishment of a fee-for-service fee schedule, much of the requested information for payors with capitated arrangements is by definition impossible to provide, such as the amount the payor is charged or was billed for a particular individual service/procedure, and the amount the lab was paid for such an individual service/procedure. Under a typical capitated contract, the payor is charged and the lab is paid on a per-member-per-month basis, not by procedure/occurrence.

2. DHCS's Proposal Seeks A Significant Amount of Data that is Not Relevant to the Formation of a Medi-Cal Fee-for-Service Fee Schedule and/or is Not Authorized by AB1494.

a. Cost of Testing Data

As noted above, cost of testing data, on a CPT-code specific level, is virtually impossible for labs to provide. Moreover, if directed to try, it is highly likely that various laboratories would attempt to allocate costs in a variety of ways. Thus, even if some kind of cost data was produced by each lab, DHCS could not do an "apples-to-apples" comparison. Moreover, and more importantly, the collection of cost data is simply not authorized by AB1494 -- which focuses on the gathering of payor payment data, not lab cost data. Finally, cost of testing data is irrelevant to DHCS's charge, which is to set a competitive fee-for-service fee schedule that is comparable to other payors. If the competitive market reimbursement amount set by other payors is determined to be $10 for a particular CPT code, then the statute requires the Medi-Cal rate to be set at around $10, *regardless* of whether the *cost* of testing for that CPT code (if it could be reliably calculated at the CPT code level, which it cannot) was $3, $5 or $9.

b. Client Data

As explained at length in Quest Diagnostics' prior written submissions, AB1494 does not authorize DHCS to seek data concerning the amounts paid by "clients," as opposed to "payors," for laboratory testing services. The statute's distinction is consistent with the fact that the client and payor markets are different in fundamental ways (as explained in Quest's September 5th submission, using hospital clients as an example). The statute therefore requires that, because Medi-Cal is a payor (and not a client), Medi-Cal's fee schedule should be keyed to the fee schedules of other payors (not clients). Moreover, it is noteworthy that DHCS itself has correctly acknowledged in its proposal that there is a difference between clients and payors, by requesting the reporting labs to indicate for each piece of data whether it pertains to a payor or a

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"providers," which are typically physicians. Also, third party "payors" do not take samples from patients. In addition, sometimes samples are drawn from a patient at a different location from the physician who orders the test.

client. Such differentiation in the data submitted should not be necessary at all, however, since DHCS is authorized by AB1494 to collect and use only "payor" data, not "client" data (and "client" data is, in any event, irrelevant).

c. Data on Capitated Arrangements

As noted above, much of the data requested in the "Capitated Rates" section of DHCS's proposed data request is impossible to provide since there is typically no "per-test" or "per-CPT-code" pricing data for capitated plans. Even more fundamentally, for the reasons explained at length in Quest's September 5th letter, "capitated" rates (like "client" rates) do not offer any 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, and we therefore do not believe that AB1494 authorizes the reporting of capitated rates. We respectfully refer DHCS back to our September 5th letter, which contains a detailed discussion of this issue. Quest Diagnostics would welcome a dialogue with DHCS about how the agency can most effectively and fairly achieve its stated goal of increasing the number of Medi-Cal patients who are subject to capitated plans. But that dialogue should be independent of the AB1494 data gathering and rate setting process, since by statute that process is confined to the fee-for-service portion of the Medi-Cal program.

The Bottom Line

We hope that this letter clearly illustrates why DHCS' preliminary proposal should be withdrawn in favor of the proposal Quest Diagnostics previously made, with widespread industry support. We strongly believe that if our original data submission proposal is adopted, DHCS will be on firm ground in making changes to its Medi-Cal laboratory testing fee schedule that will (a) bring it more in line with the fee schedules of other major third-party payors and (b) likely achieve real savings for California's taxpayers without compromising access to care for Medi-Cal beneficiaries. Quest Diagnostics stands ready to continue to participate in the stakeholder process as it moves forward over the coming months We hope that this process will be a productive one that will make it unnecessary to pursue other legislative and/or litigation options.

Sincerely,

Jean-Marc Halbout
Quest Diagnostics
West Region Vice President

Cc: Edelstein Gilbert Robson & Smith

Exhibit A

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Quest Diagnostics

August 20, 2012

By Email

Mr. John Mendoza
Acting Chief of Fee for Service and Rates Development Division
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john.mendoza@dhcs.ca.gov.

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

Dear Mr. Mendoza:

Quest Diagnostics Incorporated, the largest clinical laboratory in California, is grateful for the opportunity to participate in the stakeholder input process recently mandated by AB1494, and would like 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.

Guiding Principles

We believe that there is fundamental agreement on several key points which should guide this process. We agree that: (1) The now-suspended 51501 regime needed reform, due to its ambiguity and the heavy burden it placed on both labs and DHCS; (2) Medi-Cal should set industry-wide rates for its fee-for-service program that are competitive for such a significant third party payor while still complying with the federal access to care requirement, and (3) a new fee for service rate setting system should be developed that is fair to everyone involved and that can be implemented and administered efficiently.

We think the legislature's recent suspension of 51501 and commitment to a more simplified reporting and rate-setting process are steps in the right direction, provided the statute is interpreted and administered with these points in mind. The legislature established a stakeholder process, directed DHCS to be sensitive to the access to care requirement and other variables, and gave DHCS considerable discretion concerning what data each lab must report going forward and how that data should be used in the rate-setting process. Thus, an outcome should be possible that accomplishes our mutual goals, if we work together. Further regulatory guidance clearly is needed on the two key issues you have invited us to address: (a) precisely

what data the labs should report, and (b) how DHCS will use that data in setting new reimbursement rates. We have specific recommendations on each of these issues.

Proposed Data Reporting

With respect to what data should be reported, the bill requires reporting of "the lowest amounts other payors are paying, including other state Medicaid programs and private insurance," subject to DHCS's discretion and consideration of the access to care requirement. Given that Medi-Cal is a major third-party payor, we think the legislature clearly intended this language to mean other *third party* payors (that is, insurers such as Anthem Blue Cross and Aetna) and comparable Medicaid programs that negotiate CPT-code based fee-for-service fee schedules. It should not be read to include "clients" (which are customers, not "payors") or entities that have capitated per-member-per month arrangements. Such arrangements offer no meaningful guidance on how a fee-for-service program should set its reimbursement rates.

A significant goal of AB1494 was to get away from the kind of broad and complex reporting obligations and uncertainty that beset the 51501 regime, not to re-impose them. We believe that the goal of the legislature was to make sure that DHCS gets meaningful market data, without getting bogged down in technical issues and minutiae. Moreover, even with respect to fee-for-service third party payors of the sort clearly contemplated by the statute's reporting requirement, there are issues relating to the "lowest amount they are paying" that need further clarification from DHCS. For example, we do not think DHCS should conclude that the "lowest amount" determination should be made solely on a CPT code-by CPT code basis, without reference to the overall reimbursement contemplated under the "other payor's" entire fee schedule. We also think that DHCS should determine that the complex disallowance and denial rules of each payor should be irrelevant to what fee-for-service reimbursement *rates* should be established for Medi-Cal (especially given that Medi-Cal's disallowance and denial rules result in greater disallowances and denials than virtually any other third party payor in the state).

We also believe that it is critical that DHCS require the reporting of a data set that is clearly and objectively defined -- while still staying faithful to the statutory directive that it collect data that will capture the lowest rates set by other "payors" -- so that it can set industry-wide rates that are competitive yet fair. As already noted, the amounts labs charge their clients (such as hospitals, clinics and physician groups) should not be part of the reported data set because clients are "customers" and not "payors." Similarly, per-member-per month capitated arrangements should not be part of the reported data set because those arrangements do not provide any kind of benchmark for Medi-Cal's fee-for-service fee schedule.

Our principle recommendation is that DHCS should make the reasonable determination that large commercial insurers (with negotiating power) that have negotiated market-based, contractual fee-for-service arrangements with each lab will provide both the most meaningful benchmark data for Medi-Cal *and* the lowest rates set by other "payors."

Moreover, as further discussed below, we think DHCS will be in a much better position to determine the appropriate Medi-Cal reimbursement rate if it does not *limit* each lab's submission to some sort of "lowest amount" reimbursed by a single payor. Determining the "lowest amount" would not only be difficult for the reasons discussed above, but limiting reporting to that amount would also deprive DHCS of important benchmark data that it could and should capture by requiring the reporting of the *entire fee schedule* of the most competitive payors. Moreover, this broader set of data from such major payors would also likely still satisfy the statutory requirement that "lowest amounts" from other payors be included in the reports.

So, our proposal is that DHCS should require each lab to submit the largest five contractual fee schedules (on a CPT code basis) that it has negotiated with fee-for-service insurance carriers in California (in which the lab is contracted as a participating lab provider) that are in effect on a specified date during the reporting period. It should be possible to develop a spreadsheet for such reporting so that DHCS can analyze it any way it wishes, and Quest Diagnostics would be willing to work with DHCS on the development of such a spreadsheet.[1] In addition, because Quest Diagnostics and most other labs should be able to report not only the selected insurer's negotiated CPT-code specific fee schedule but also the volume of tests reimbursed by that insurer, on a CPT code basis, we recommend that such volume utilization reporting for the top fee schedules should also be required. That way, if DHCS wishes to do weighting or averaging as part of its rate setting analysis (which we also recommend), it will have the data needed to do so.[2]

As far as AB1494's requirement that labs also report the amounts that other state Medicaid programs are paying, we frankly think this data is not very useful. Different economic conditions in other states can make their Medicaid rates inapplicable to California. States with a lower cost of living are likely to have lower reimbursement rates, and vice versa. Nevertheless, because the trailer bill requires some (undefined) reporting of other Medicaid rates, we

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[1] Please note that we think that requiring the reporting of the insurer's entire published fee schedule is most appropriate, as opposed to requiring labs to attempt to calculate and report the carrier's "net" payment amount per CPT code after disallowances. This is because (a) disallowances are usually made on a CPT code specific basis, so that a single denial would make "zero" the lowest net payment amount for most CPT codes (not a useful benchmark), and (b) because it would be very difficult to allocate such CPT code specific disallowances over the typical group of tests involving multiple CPT codes that patients often have performed simultaneously. If a contractual arrangement subject to reporting includes across-the-board or volume discounts from a published fee schedule, however, then the reported fee schedule for that carrier should either include the across the board discount or otherwise disclose the discount arrangement.

[2] Of course, all data reported by any lab should be kept confidential from other labs and from the public, as it is competitively sensitive information. AB1494 suggests that DHCS use an auditor to collect and assist in analyzing the data, and reporting the data to a reputable auditor under a strict confidentiality agreement should also help to insure that it is kept confidential.

recommend that DHCS select a small group of other states that it believes are most comparable to California and then develop a way to obtain their reimbursement rates, either directly or through some cooperative arrangement with the California labs that also do business outside of California.

Finally, we recommend that following the stakeholder process and the submission by each lab of its first set of data on December 27, 2012 as described above, DHCS require that each lab submit a second set of updated data before the new Medi-Cal rates are set. The new statute requires that the first set of data be for the year 2011, but contemplates that the new Medi-Cal reimbursement rates will not be set until 2013. We think that DHCS should ask each lab to submit *2012* data on or about April 1, 2013, so that DHCS can base its new Medi-Cal fee schedule on its examination of both 2011 and 2012 data.

Use of Reported Data in the New Rate Setting Process

With respect to how the reported data described above should ultimately be used by DHCS in setting its industry-wide fee-for-service reimbursement rates under the new regime contemplated by AB 1494, we urge DHCS to view the reported fee schedules in their entirety, rather than using what we refer to as the "cherry-pick" approach. Under the "cherry-pick" approach, DHCS would set its published Medi-Cal reimbursement rate for each CPT code by picking the lowest rate for that CPT code set by any other payor. This would inevitably result in an overall Medi-Cal fee schedule that is far lower than any other payor's, which would be entirely inconsistent with the law.

The following hypothetical illustrates the unacceptable results that would come from adopting a "cherry-pick" approach. Assume that a lab's largest three negotiated third-party payor fee schedules are with Insurer 1, Insurer 2 and Insurer 3, and that (for simplicity) each payor reimburses for three CPT codes (A, B and C) once, at the rates reflected in the table. The last column is the fee schedule that would result for Medi-Cal if it used a "cherry-pick" approach (which we believe would be entirely unsupportable).

Insurer 1	Insurer 2	Insurer 3	Medi-Cal
A: $5	A: $10	A: $10	A: $5
B: $10	B: $5	B: $10	B: $5
C: $10	C: $10	C: $5	C: $5
Total: $25	Total: $25	Total: $25	Total: $15

Under the hypothetical, Medi-Cal's total reimbursement for all three tests would be $15, whereas each of the other payors would reimburse $25 for the exact same three tests. Such significantly under-market Medi-Cal rates would cause labs to disfavor treatment of Medi-Cal patients, severely limit access to care by those patients, and would be inconsistent with the directive in AB1494 that DHCS ensure a rate methodology that complies with the federal Medicaid access to care requirement. Moreover, as a practical matter, such a fee schedule would be opposed by Quest Diagnostics and the rest of the California lab industry, as well as by patient advocacy groups, and would not be approved by CMS or the courts. A key reason why we think

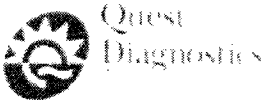
DHCS should require each lab to report its 5 largest negotiated insurer fee schedules **in their entirety** is that DHCS will then have the data needed to make informed and intelligent decisions about what rates are fair and competitive for Medi-Cal. If it has such comprehensive rate data on a CPT-code basis from many labs, especially if it also includes CPT-code specific utilization data, then DHCS will be able to analyze and weight the data appropriately, discard outliers, and develop a rate schedule that will be consistent as an overall matter with other large insurers with market power, and consistent with the law.

We hope that this letter provides some helpful input to DHCS at the outset of 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

Exhibit B



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September 5, 2012

By Email

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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.

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[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

CONFIDENTIAL INFORMATION Concerning Contracted Fee Schedule #1
FROM: INSERT NAME OF LABORATORY
Time Period: Jan 2011 - Dec 2011

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.
1234	ABC	50,000	$5.00	N
2345	BCD	60,000	$20.00	N
3456	EFG	20	$4.00	N
4567	HIJ	20,000	$10.00	N
5678	KLM	10,000	$30.00	N

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."

CONFIDENTIAL INFORMATION Concerning Contracted Fee Schedule #2
FROM: INSERT NAME OF LABORATORY
Time Period: Jan 2011 - Dec 2011

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.
1234	ABC	50,000	$5.00	N
2345	BCD	60,000	$20.00	N
3456	EFG	20	$4.00	N
4567	HIJ	20,000	$10.00	N
5678	KLM	10,000	$30.00	N

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."

CONFIDENTIAL INFORMATION Concerning Contracted Fee Schedule #3
FROM: INSERT NAME OF LABORATORY
Time Period: Jan 2011 - Dec 2011

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.
1234	ABC	50,000	$5.00	N
2345	BCD	60,000	$20.00	N
3456	EFG	20	$4.00	N
4567	HIJ	20,000	$10.00	N
5678	KLM	10,000	$30.00	N

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."

CONFIDENTIAL INFORMATION Concerning Contracted Fee Schedule #4
FROM: INSERT NAME OF LABORATORY
Time Period: Jan 2011 - Dec 2011

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.
1234	ABC	50,000	$5.00	N
2345	BCD	60,000	$20.00	N
3456	EFG	20	$4.00	N
4567	HIJ	20,000	$10.00	N
5678	KLM	10,000	$30.00	N

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."

CONFIDENTIAL INFORMATION Concerning Contracted Fee Schedule #5
FROM: INSERT NAME OF LABORATORY
Time Period: Jan 2011 - Dec 2011

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.
1234	ABC	50,000	$5.00	N
2345	BCD	60,000	$20.00	N
3456	EFG	20	$4.00	N
4567	HIJ	20,000	$10.00	N
5678	KLM	10,000	$30.00	N

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."