

HOOPER, LUNDY & BOOKMAN, INC.

LAWYERS

ROBERT W. LUNDY, JR.
PATRIC HOOPER
LLOYD A. BOOKMAN
W. BRADLEY TULLY
JOHN R. HELLOW
ANGELA A. MICKELSON
LAURENCE D. GETZOFF
DOUGLAS S. CUMMING
JAY N. HARTZ
BYRON J. GROSS
TODD E. SWANSON
PATRICIA H. WIRTH
GINA REESE
DAVID P. HENNINGER†
REBECCA K. LAMBETH
RICHARD J. BABCOCK
RINA J. PAKULA
JONATHAN F. ATZEN

WATT PLAZA, SUITE 1600
1875 CENTURY PARK EAST
LOS ANGELES, CALIFORNIA 90067-2799
TELEPHONE (310) 551-8111
FACSIMILE (310) 551-8181

SACRAMENTO OFFICE
400 CAPITOL MALL, SUITE 2400
SACRAMENTO, CALIFORNIA 95814
TELEPHONE (916) 447-0203
FACSIMILE (916) 447-0502

December 5, 1994

WRITER'S DIRECT DIAL NUMBER

(310) 551-8160

†ALSO ADMITTED IN THE STATE OF MARYLAND

Anne K. Bingaman, Assistant Attorney General
U.S. Department of Justice
Antitrust Division
Office of the Assistant Attorney General
Washington, D.C., 20530

Re: Preferred Laboratory Access
Network: Multiprovider Network
Business Letter Review

Dear Ms. Bingaman:

We hereby submit this request on behalf of Preferred Laboratory Access Network ("PLAN") for a statement by the Department of Justice ("DOJ") regarding its present enforcement intentions regarding PLAN's proposed activities pursuant to the DOJ's business review procedures, 28 C.F.R. Section 50.6. All relevant data, including background information, complete copies of all operations documents and detailed statements of all collateral/oral understandings accompany this request.

I. BACKGROUND

A. General Information Regarding PLAN

Preferred Laboratory Access Network is the joint endeavor of a number of California clinical laboratories which are responding to payor needs for laboratory provider networks.¹

¹ A list of PLAN's sixteen present members is attached hereto as Exhibit A. PLAN's articles of incorporation are attached as Exhibit B, and its bylaws are attached as Exhibit C.

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PLAN was incorporated on January 3, 1994, and has been organized under California law as a nonprofit mutual benefit corporation.²

PLAN was initiated by a number of smaller clinical laboratories out of a concern that, due to the large areas of geographic coverage which are expected to be required by managed care agreements, they would be unable to effectively compete with larger laboratories to obtain such contracts. By affiliating through an entity such as PLAN, these laboratories are able to present a delivery system with much greater geographic coverage, and therefore will be able to effectively compete with larger laboratories for managed care contracts.

Membership in PLAN will not be open to all clinical laboratories. Rather, although initial membership determinations were based upon expressions of interest, future membership decisions will take into account PLAN's need, or lack thereof, for additional coverage or capacity in given areas. In addition, membership decisions will take into account any market share limitation suggested by DOJ's response to this letter.

The principal benefit which will result from PLAN is cost savings resulting from enhanced competition by laboratories for payors seeking to contract for laboratory services on a regional, statewide or county basis on either a capitated or discounted fee-for-service basis. In addition, over time, it is anticipated that PLAN's information systems will allow PLAN to generate and provide payors with access to data pertaining to utilization of services and outcomes. This data will allow PLAN to develop laboratory testing protocols which will better rationalize the ordering of clinical laboratory testing and thereby help to control the costs of laboratory testing. The development of such systems is believed by PLAN to be beyond the ability of its individual members.

B. PLAN Is A Response To Changes In California's Medi-Cal Program.

PLAN has been formed in response to the growth of managed care plans in California and, most immediately, as a

² As an entity not yet operational, PLAN does not presently maintain a place of business. However, PLAN's general mailing address is 811 South San Fernando Boulevard, Burbank, California 91502. It is nevertheless requested that DOJ's response to this inquiry be directed to the undersigned.

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direct response to state initiatives under the Medi-Cal program (California's Medicaid program). These Medi-Cal changes, which are detailed below, are expected to help control the escalating costs of California's provision of medical care to the poor and needy.

As you may be aware, California's Medi-Cal program is being transitioned in thirteen key counties containing approximately one half of the state's Medi-Cal beneficiaries from a traditional fee-for-service model into a managed care model. In these counties, the traditional Medi-Cal delivery system (pursuant to which patients and their physicians have chosen laboratory service providers) will be replaced with direct contracts between providers and the counties, with Medi-Cal beneficiaries generally being required to obtain services from the contracted providers.

In addition, legislation has been enacted in California which requires the Medi-Cal program to implement a competitive contracting system with respect to the Medi-Cal beneficiary population for which the managed care initiative is inapplicable. Under this system, providers of laboratory services will negotiate discounted fee-for-service contracts directly with the California Department of Health Services.

PLAN's immediate objective is to seek to provide laboratory testing for Orange County's Medi-Cal managed care system, known as OPTIMA. The OPTIMA system, which is presently under development, is expected to begin the process of contracting with providers in mid-January, 1995, and Orange County is expected to be one of the first California counties in which the new managed care initiative will be implemented. A similar system is scheduled to be implemented in Los Angeles County, and Los Angeles County is expected to be the subject of PLAN's second phase of contracting efforts.

Orange County and Los Angeles County, as well as other counties which will participate in the Medi-Cal managed care initiative, have made it clear that they will contract with only a limited number of providers, and, except with respect to emergency services, non-contracting providers will not be reimbursed for providing services for Medi-Cal beneficiaries who

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are enrolled in the managed care plans.³ In fact, Los Angeles County has reportedly taken the position that it will contract with only a single provider of services.

Although PLAN's initial efforts are expected to focus on capitated and fee-for-service contracting opportunities with county governments and the State of California, PLAN will also pursue contacting opportunities with health maintenance organizations, indemnity insurers and self-insured systems.

II. PLAN'S CONTRACTING MODEL

PLAN will seek contracting opportunities both on a capitated and on a fee-for-service basis. As is discussed below in more detail, PLAN will operate using the "joint venture" and "messenger" models which have been successfully used by physicians in addressing the antitrust concerns which might otherwise result from their concerted managed care activities.

A. Capitated Contracting Arrangements.

With respect to payors offering capitation, PLAN will negotiate a capitation rate in return for which it will obligate itself to provide clinical laboratory testing services for the payor's patients.

PLAN will deliver these services by subcontracting with its member laboratories, who will be obligated to service capitated contracts entered into by PLAN.⁴ Payment will be made to these laboratories by PLAN's allocating total monthly capitation amounts received among its members based upon the respective volume of service performed during the month by each member.

³ This is similar to the Medi-Cal contracting program which Medi-Cal has had in place since 1984 with respect to inpatient services provided by hospitals.

⁴ Any member who does not accept a particular capitated rate approved by PLAN's board of directors will be free to terminate its membership in PLAN and its contract with PLAN with respect to capitated services. However, members will not be free to pick and choose among capitated agreements negotiated by PLAN.

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For purposes of these allocations, services will be valued at rates from time-to-time established by PLAN's board of directors. PLAN's present intent is that the Medi-Cal fee schedules will be used as the weighting factors for the purpose of making these allocations. Of course, this will not necessarily result in members receiving the Medi-Cal fee schedule amounts since total capitated receipts will be allocated over all services provided. DOJ has recognized that the manner of dividing revenues among the participants in a network of financially integrated providers does not raise antitrust issues.⁵

Thus, PLAN's capitated contracting mechanism will put each PLAN member at financial risk since the reimbursement to each member will be contingent upon the amount of capitation payments received by PLAN from third-party payors and, more importantly, because the amount received by each member from PLAN will necessarily be reduced to the extent that other members are paid by PLAN for services rendered to covered enrollees. Accordingly, PLAN has an incentive to control the utilization of laboratory services.

Based upon the foregoing, PLAN believes that its activities will result in cost savings associated with the assumption of financial risk by its participating laboratories. Improved utilization review, case management and quality assurance are also expected to result as secondary efficiencies.

B. Fee-For-Service Contracting.

To the extent that PLAN pursues contracting opportunities on a fee-for-service basis with the Medi-Cal program and others, it will do so using the so-called "messenger model."⁶ In essence, the PLAN contracting officer (who will be an agent of PLAN, and who will not be an employee, principal or director or officer of any PLAN member) will solicit fee-for-service payment offers from third-party payors and convey such offers to PLAN's participating members. Such offers will then be

⁵ See September 27, 1994 Statements of Enforcement Policy and Analytical Principles Relating To Health Care And Antitrust, fn. 34, p. 93.

⁶ This approach is generally described at pages 94-96 of the September 27, 1994 Guidelines.

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approved or disapproved individually and unilaterally by each PLAN member without consultation with one another.⁷

It is possible that the contracting officer will also act as a facilitator of payor-member negotiations by conveying member price offers to third-party payors. However, with regard to price terms, the contracting officer will act strictly in the role of an intermediary to facilitate the exchange of offers, and will not act a price negotiator for PLAN's membership, either individually or collectively. To avoid any appearance of concerted activity with regard to price terms in connection with fee-for-service contracting, PLAN will inform payors of the limits of the role of the contracting officer.

Again, PLAN members will not coordinate such offers with respect to price terms, either among themselves or through the contracting officer. In particular, with respect to price terms, the contracting officer will not coordinate individual provider responses to a particular proposal, disseminate to members any other laboratory's views or intentions as to payor proposals, or otherwise act as an agent for collective negotiation of agreements or to facilitate collusive behavior among PLAN members. Because no price information concerning fee-for-service contracts will be shared among PLAN's members, risk of "spill over" collusion with respect to members pricing under contracts independent of PLAN should be eliminated.

It is contemplated that PLAN may seek to establish nonprice terms related to member contract obligations, such as those pertaining to utilization review and quality assurance and laboratory reporting procedures on a collective basis. Indeed, agreements among PLAN's members with respect to such parameters may be necessary in order to allow PLAN to foster consistency and to facilitate PLAN's interactions with payors. A PLAN member will not be required to adhere to such standards in any setting other than its capitated contracts with PLAN or its fee-for-

⁷ PLAN's members will be free to participate in PLAN's discounted fee-for-service contracts on a individual contract basis. Acceptance of a contract will require an affirmative response from each laboratory. If a laboratory fails to respond to the payor's offer with respect to a proposed contract, that laboratory will be deemed to have rejected the proposed contract, but will be permitted to continue to participate as a PLAN member with respect to capitated contracts and fee-for-service contracts with other payors.

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service contracts obtained through the auspices of PLAN's contracting officer.

C. Competition Within PLAN.

Although capitated pricing for laboratory services will be established pursuant to the joint venture mechanism previously discussed, PLAN members will continue to compete with one another on service, quality and other non-price terms for the enrollees under PLAN contracts. This is because PLAN itself will not allocate particular testing responsibilities to its members. Rather, PLAN members will make unilateral decisions with respect to the geographic and service markets they will serve. Physicians and patients will be free to choose any laboratory within PLAN's network for those services included in a PLAN capitated contract with a payor.

Likewise, given the nature of the "messenger model," it is clear that PLAN's members will remain in competition with respect to price in connection with PLAN's fee-for-service contracting activities. PLAN members will also compete with respect to quality and service under such contracts.

Further price competition will exist among PLAN's members even with respect to capitated contracts established by PLAN because PLAN will not impose exclusivity requirements upon its members. Rather, PLAN's member laboratories will be free to contract individually with third-party payors outside the framework of PLAN, and to participate in other laboratory service contracting organizations which compete with PLAN for third-party payor contracts.⁸ No agreement or coordination will occur through PLAN among PLAN's members with respect to capitated fee-for-service contracting opportunities which they may elect to pursue independent of PLAN.

Of course, PLAN's members will also remain in active competition with one another for traditional laboratory business which is not governed by managed care type contracts. Such business is expected to comprise the majority of the revenue of PLAN members for the foreseeable future.

⁸ Unless DOJ requires otherwise as a condition of issuing a favorable business review letter, PLAN may seek exclusive capitated and fee-for-service contracts with third party-payors.

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III. PLAN'S MARKET SHARE

A. General Nature Of Clinical Laboratory Testing Market.

PLAN's members represent a significant number of laboratories and locations. However, given the large number of clinical laboratories in California, it appears that the laboratory services market is not one which is highly concentrated.

Unlike the physician services market, in which HMOs have chosen to deal with providers primarily through fully integrated multi-physician groups and IPAs, HMOs to date have contracted with laboratories on an individual basis. Competition for laboratory testing contracts with HMOs and other managed care payors is intense, both because of the managed care volume itself, but also because serving a physician's managed care patients is often viewed by a laboratory as a possible means to gain access to a physician referrals for private pay testing as well.

PLAN expects to face unrelenting price competition from national, statewide and regional laboratories, and the force of this competition will prevent PLAN from having any ability to move pricing above competitive levels.⁹ Because of the many laboratories within PLAN's service area which are not PLAN members which will compete with PLAN directly or form competing laboratory networks, it appears PLAN will not have market power. This is especially true in light of the fact that a small number of large competing laboratories would be able to handle the testing volume expected by PLAN.

In addition, as previously discussed, PLAN's own members are likely to seek to contract directly with payors should PLAN seek noncompetitive levels of pricing in capitated contracts. Because laboratory testing is ordered by physicians, and is not generated by the member laboratories for one another, PLAN would not have any effective means of discouraging such internal competition.

⁹ PLAN's competitors will include large national and regional laboratories which are active in California such as Unilab, SmithKline Clinical Laboratories, Damon Clinical Laboratories, Physicians Clinical Laboratory and Allied Clinical Lab.

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B. The Number Of Clinical Laboratories In California.

Information which has been provided to PLAN by the Laboratory Field Services Division of the California Department of Health Services ("DOHS"), the agency responsible in California for regulating and licensing clinical laboratories, indicates that there are approximately two thousand licensed clinical laboratories in California. Of these licensed laboratories, DOHS reports that approximately 26% are independent clinical laboratories (*i.e.*, are not operated as part of a hospital or as part of a medical practice), 55% percent are owned by hospitals, 12% are owned by physicians and the remaining 8% are operated by HMOs. PLAN's membership therefore represents less than one percent of the number of licensed laboratories in California.¹⁰

C. PLAN's Estimated Market Share.

Because individual laboratories serve areas of widely differing size, and because laboratories have substantially different gross revenue volumes, PLAN has surveyed its members and had them report data to legal counsel (on a confidential basis where members do not have access to each others' submissions) as to their gross sales in each California county. Counties were assumed to be the smallest relevant markets because many laboratories, including most PLAN members, provide services in multiple counties. The sum of these numbers provides the numerator for PLAN's estimate of the market which is represented by its members.

The denominator (*i.e.*, the total market volume) was estimated by first fixing the total California volume of clinical laboratory services at approximately \$3.5 billion. This number comes from market research which has been conducted by securities analysts in connection with their offerings of stock in publicly-traded laboratories. Of this \$3.5 billion, it has been estimated by securities analysts that approximately \$950 million represents testing by independent clinical laboratories, \$1.73 billion represents hospital testing and \$820 million represents physician

¹⁰ Because DOHS' longstanding practice has been to not require physicians who operate clinical laboratories to obtain licensure unless they are in a group of five or more physicians, the actual number of clinical laboratories in California greatly exceeds the number of licensed laboratories. It has been estimated that there may be as many as sixteen thousand physician operated clinical laboratories in California.

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office testing. This estimated \$3.5 billion statewide market was then allocated among each of California's counties based upon their respective populations, thereby providing an estimate of the total volume of laboratory services performed in each county.¹¹

We have attached as Exhibit D a chart showing PLAN's estimate of the market share of its members in each California county using the previously described methodology. Based upon its survey, PLAN believes that its members presently represent no more than fifteen percent of the dollar volume of laboratory services rendered in any county targeted by PLAN and that, because its members participate on a non-exclusive basis, DOJ should not have market power concerns as a result of PLAN's activities.

In recognition of the fact that physician office laboratories are not well situated to handle high volume HMO contracts, PLAN has also made market share estimates using the conservative assumption of excluding physician office laboratories as potential competitors. Rounding the estimated volume of physician office testing from \$820 million to \$1 billion, PLAN has also generated market share estimates assuming a total market of \$2.5 billion. As Exhibit D shows, PLAN's market share even under this scenario is insufficient to give rise to antitrust concern.¹²

¹¹ This method assumes that the incidence of use of laboratory testing services is constant per person throughout the state.

¹² It might be argued that some further adjustment would be appropriate to take into account the fact that much hospital testing is for inpatients and that such testing may not be part of the volume which would be subject to laboratory services agreements with HMOs and other payors, but instead is wrapped up in the overall hospital services contract with the payor. However, PLAN believes that hospital-based and so-called independent laboratories should be considered to be competitors since both perform laboratory tests. Moreover, many hospitals operate substantial outpatient laboratory testing programs. In any case, PLAN does not presently have reliable data regarding the volume of testing which is performed for hospital inpatients.

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In addition, as discussed below, PLAN believes that use of a larger market in the Southern California area is supported by several features of the clinical laboratory industry.

The clinical laboratory industry functions primarily through large centralized laboratories which serve large geographic regions. There is no need for a patient to go directly to the laboratory which performs the test. Rather, the point of access to laboratory testing is the physician's office or, in many instances, a specimen collection station maintained by the laboratory. Laboratories maintain relationships with many physician offices by which they pick up specimens. Laboratories also maintain strategically located patient service centers where patients may go to have specimens collected. Setting up courier routes and establishing drawing stations in themselves require little capital.

In addition, due to the high capacity of automated equipment which is in use for most laboratory testing, a laboratory's marginal cost of performing additional testing is quite small. Thus, costs of "ramping up" to service additional volume are normally small since additional equipment is normally not required.

PLAN therefore submits that there are relatively low barriers to entry in the clinical laboratory testing market once a basic laboratory has been established. Accordingly, adjacent laboratories can be expected to readily reach into any market in which PLAN might try to raise prices for capitated contracts above competitive levels.

Based upon the foregoing, and due to the fact that laboratories in Los Angeles County typically do substantial business in Orange County and San Diego County and laboratories in San Diego County do substantial business in Orange County and Los Angeles County, it appears to be more accurate to consider these three counties to be a single market. When considered on this basis, the market share of PLAN and/or its members would be quite small, even when using the more conservative \$2.5 billion total market estimate.

PLAN will monitor its membership on an ongoing basis with the goal of representing no more than thirty percent of the laboratory sales volume in any given geographic market. Given the extensive competition which will continue to exist among PLAN's members (as described in Section II.C. above) and the nature of the laboratory market described in this section, PLAN

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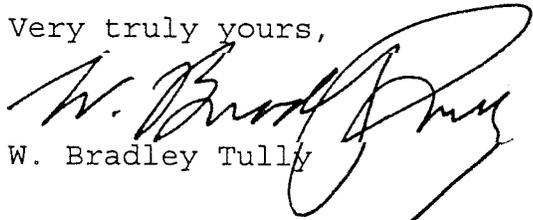
believes that such market share will pose no danger to competition.

However, given PLAN's need for broad geographic coverage and the diversity of the markets in which PLAN will operate, this threshold might in some instance be exceeded where a single PLAN member represents a greater share of sales within a given market. PLAN will endeavor to ensure in such instances that it has no other member which is a competitor of the laboratory in question. PLAN submits that this adequately alleviates any concerns that might otherwise exist from an accumulation of combined market power since PLAN, in such instances, would not alter the market position of any existing laboratory provider.

* * *

We look forward to your response regarding this matter. Please call me if you have any questions or comments.

Very truly yours,


W. Bradley Tully

WBT:cc