Developing Medicare Competitive Bidding: A Study of Clinical Laboratories

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Competitive bidding to derive Medicare fees promises several advantages over administered fee systems. The authors show how incentives for cost savings, quality, and access can be incorporated into bidding schemes, and they report on a study of the clinical laboratory industry conducted in preparation for a bidding demonstration. The laboratory industry is marked by variable concentration across geographic markets and, among firms themselves, by social and economic heterogeneity. The authors conclude that these conditions can be accommodated by available bidding design options and by careful selection of bidding markets.

INTRODUCTION

Since 1983 when Medicare adopted hospital prospective payment, the program has moved from retrospective reimbursement to prospective fee schedules in the fee-for-service (FFS) sector. Dissatisfaction with cost increases under retrospective payment led policymakers to adopt fee schedules for laboratory services and durable medical equipment in the mid-1980s and the Medicare physician fee schedule in 1992. The 1997 Balanced Budget Act (BBA 1997) further reinforced the movement away from cost-based payment by mandating prospective payment for hospital outpatient services, skilled nursing facility days, home health agency services, and rehabilitation hospitals. All of these recent and forthcoming systems are examples of administered fee-setting.

The administered fee-setting systems appear to have moderated cost growth. But administered prospective fees are not very flexible in the face of changing market conditions. In the ideal—a perfectly competitive market—optimal prices result from market participants' myriad decisions in response to changes in preferences, income, technology, input prices, and other factors. The essential problem for administrators in setting optimal prices is obtaining adequate information about the direction and magnitude of market forces—particularly production costs or the economic and technological forces driving them. This problem is complicated by producers' reluctance to reveal information helpful to the administrators (Hoerger, Waters, and Sloan, 1991). Without detailed market information, administered prices are unlikely to adequately reflect cost-decreasing or -increasing trends.

Thus, an administered fee schedule may quickly become outdated. This is especially true in industries marked by technological innovation and flexible labor markets.[1] Adoption of cost-reducing technology may not translate into lower prices in a timely manner— or ever. If prices are rigid and initially above cost, increasingly inefficient producers may enter the market until costs rise to equal price, whereas entry should normally lead to lower prices. Nor can rel-

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[1] In principle, no Medicare service category is immune from the problem of obtaining adequate and timely information to update administered fees. It has been suggested, for example, that Medicare could benefit from using competitive bidding to revise physician payment rates (McCombs, 1989).

ative prices move freely in response to changes in costs. This may create incentives to over- or undersupply particular services, causing an inappropriate overall mix of services.

These disadvantages of administered fee schedules warrant Medicare's consideration of a more market-based approach to fee-setting. Competitive bidding is one potential market-based approach. It motivates producers to engage in direct market competition in exchange for increased volume. The bidding itself can reveal the lowest price that producers are willing to accept—the essential summary of market forces needed by fee administrators.

A particularly attractive feature of bidding is the dynamism and flexibility it can introduce. Frequent bidding allows for timely incorporation in prices of either cost-reducing or cost-increasing trends, thus assuring a competitive rate of return to capital. This contrasts with the blunt tool of market-basket indexing often used in prospective payment systems. In general, competitive bidding obviates the need for administrative proceedings intended to adjudicate whether and how much costs are changing. Under competitive bidding, if fees are initially set too high, new suppliers will participate in subsequent competitions, and prices will fall. Prices resulting from competitive bidding should reduce incentives to supply excessive services or the wrong mix of services.

Medicare has long recognized these potential advantages of competitively derived pricing. In the mid-1980s, the Health Care Financing Administration (HCFA) began to plan a bidding demonstration for laboratory services and durable medical equipment. From the start, however, the initiative was highly controversial. The supplier, laboratory, and medicine communities voiced fears that competitive bidding would cause unacceptable quality losses. As a result, in 1987 Congress imposed a multiyear funding moratorium on the activities.

HCFA resumed planning for the projects in 1995. By that time, the climate seemed more favorable. Competitive bidding was being successfully and widely used by private managed care organizations (MCOs) and others, including government agencies, to purchase laboratory and other health services at reduced fees. Further, the Clinton Administration and Congress included competitive bidding provisions for Medicare in their respective 1995 budget proposals.[2]

The developmental work begun a decade earlier left a foundation on which to rebuild the projects (Mennemeyer et al., 1987; Mennemeyer and Reardon, 1989; Hoerger, Waters, and Sloan, 1991; Hoerger and Waters, 1993). The groundwork included analysis of options for the bidding scheme to promote incentives for cost savings and quality. Options concerned such elements as the choice of services to put up for bidding, the unit and scope of bidding, pricing approaches, and winner selection procedures. The analysis showed how certain properties of the services in question, such as unit cost, might support a given option to promote cost or quality objectives. Administrators' choices might also consider values in the sociopolitical culture, such as the freedom to choose one's provider. An important general implication was that Medicare should probably avoid adopting the winner-take-all approach typical of many commercial and governmental bidding competitions.

With the bidding principles basically established, in late 1995 HCFA set out to translate them into a workable operational

[2] Subsequently, in 1997 the Balanced Budget Act explicitly mandated demonstrations of competitive bidding for Medicare Part B services, excluding physician services. The selection of services was left to the discretion of the Secretary of Health and Human Services. Congress also legislated a demonstration of competitively priced rates for Medicare health maintenance organization (HMO) contracts.

plan for laboratory services.[3] The implications of Medicare's theoretical options needed investigation in the context of the laboratory industry of the 1990s. Thus, it was necessary to explore the laboratory environment further. The research issues addressed in this article, however, are generic to launching Medicare competitive bidding for a range of services in the FFS sector. These issues confront Medicare whether bidding is conducted experimentally or routinely as part of the Medicare program.

The first research issue concerned the extent to which the industry's current organization can comfortably accommodate competitive bidding—a question separate from the conceptual one of the suitability of laboratory services per se. As we framed it, this issue concerned the industry's potential for engaging in meaningful competition, as well as topical questions of current business conditions. We pursued this from several perspectives, reviewing the laboratory industry's general organization, recent developments in antitrust regulation, examples of relevant public- and private-sector payment arrangements, and current financial status. A second issue concerned the scope of bidding—that is, deciding on a manageable group of procedures to put up for bidding, one whose constituents do not seriously violate principles laid out in the developmental work. Given the tests currently used in Medicare and their interrelationships, could we find a cohesive, parsimonious set for which competitive prices could have a large impact on Medicare's expenditures? A third issue concerned the selection of market venues for bidding. Laboratory markets, with the exception of the market for esoteric[4] tests, are local or regional. Our findings from the inquiry into national industrial organization suggest that not all areas would be equally well suited to host a successful competition. Thus, for an area that appeared promising from preliminary data, we wanted to assess in detail the competitive potential of the firms in the market. We examined the market's size, the number of potential bidders, their role in the market, their product mix, their Medicare market shares, and their market service areas within the broader geographic unit. The information in toto would allow inferences on a local industry's potential for engaging in competition leading to lower prices without adverse impact on service quality or access to care.

In the following section of this article, we review several key options for the bidding scheme and show why certain choices appear justifiable in the case of laboratory services. These choices must take into account Medicare's uniqueness as a payer. Medicare is the single largest health care payer, with extraordinary market power. It is supposed to be an impartial government bureaucracy adhering to equity principles in dealing with providers as well as beneficiaries. It also embodies a "social contract" with the American people. We explain why some options are harder for Medicare to ignore, compared with other purchasers, such as private managed care companies. We also comment on the suitability of laboratory services per se for competitive bidding.

In the next section, we describe the data and methods we used to study industry conditions, research the scope of bidding, and perform the market analysis. It is fol-

[3] A demonstration of competitive bidding for durable medical equipment was launched separately. At this writing, HCFA has made no final decisions on the location, effective date, and final design of the laboratory and durable medical equipment demonstrations. Any future national implementation of competitive bidding, if authorized, will undoubtedly be informed by the demonstration experiences but may not necessarily use their same specific designs.

[4] Esoteric tests are relatively uncommon, non-standardized procedures that tend to be very dependent on interpretation skill, making results more variable across laboratories than other classes of tests. Examples include most cytogenetic tests (e.g., chromosome analysis) and tumor markers for breast cancer using polymerase chain reaction.

lowed by the research findings. The final section discusses the implications of the research for implementing competitive bidding in the laboratory arena. Only through the specific industry knowledge gained in the study is it possible to draw implications in view of Medicare's unique needs and purposes.

DECISIONS FOR CONDUCTING MEDICARE COMPETITIVE BIDDING

From a purchaser's perspective, key decisions in formulating an approach to competitive bidding concern the exclusivity of the outcome, the selection of other incentives to motivate attractive bids, and the unit and scope of bidding. An additional practical consideration is whether to exempt some suppliers from bidding.

Exclusivity of the Outcome

Important bidder incentives stem from the purchaser's decision about how many suppliers will remain after the competition is concluded. Fundamentally, the decision involves a tradeoff of Medicare fee reductions against quality and access gains. Potentially, the decision may have broader economic and sociopolitical implications—impacts that can threaten competitive bidding as a policy endeavor, unless they are considered in the decisionmaking.

The most restrictive outcome—a single supplier—offers the strongest incentive to bid low prices, because the winning bidder can assume growth in market share, and the firm may be able to realize economies of scale. An additional advantage for the buyer is the possible benefit from structuring an exclusive relationship with the winner, catering to the buyer's unique needs. Further, administering the payment function is apt to be simplified with a single supplier, potentially saving the government resources. Because of Medicare's huge size—it accounts for about one-third of the market for many health services—a single supplier would need unusually large capacity. Nevertheless, for some services such an arrangement is conceivable. With laboratory services, for example, several extremely large firms each may have the capacity individually to meet Medicare supply needs in many markets.

A multiple-supplier outcome implies weaker incentives to bid low prices, because market-share growth is not guaranteed. Rather, the suppliers would have to compete for market share after the conclusion of the bidding.[5] As the number of suppliers grows, not only does the incentive for aggressive bids tend to weaken, but also the range of acceptable price offers tends to expand at the high end, causing increases in the competitively derived fees. Administering payments also becomes more complicated with multiple suppliers.

However, competition for market share can result in quality enhancement beyond the minimum established for purposes of conducting the bidding (Hoerger and Waters, 1993). If a single supplier is selected, this mechanism to ensure quality is unavailable. The problem of quality assurance can be particularly serious if Medicare cannot easily establish a desired level of quality, measure it, and enforce it. For example, the quality of broad or complex services such as office visits for physician services is difficult to characterize objectively. A single winning supplier for such complex services is probably inappropriate, because of the risk to quality. In contrast, with durable medical equipment and clinical laboratory services, quality measurement appears feasible. For example, measures of laboratory-test accuracy

[5] In some schemes market share could be allocated to multiple suppliers, but this arrangement is not advantageous for the buyer, as the discussion makes clear.

are available, and measures of service such as the timeliness of test results can be collected and verified.

When the costs of quality monitoring are considered, a multiple-supplier outcome might have a more favorable impact on administrative costs than a single winner. This is because quality-monitoring costs with a single supplier might be high relative to prices. With laboratory services, for example, unit prices are among the lowest paid by Medicare.[6] By obliging suppliers to compete over quality, some monitoring expenditures can be saved. Because of Medicare's large size, the savings are potentially significant.

It can be argued that a multiple-supplier scheme is always preferable, if only to ensure the more subjective aspects of quality (Mennemeyer et al., 1987). Medicare may wish to depend on physicians and beneficiaries to exercise their judgment over these aspects at the point of sale. For example, physicians sometimes request informal consultations from laboratories about testing decisions. The perceived competence and responsiveness of the laboratory personnel can vary among physicians. The role of physician and beneficiary judgment means that Medicare has less to gain than a typical commercial buyer from an exclusive partnership that is finely tailored to meeting the purchaser's needs. Moreover, protecting the discretion of physicians and beneficiaries to the greatest practical extent has value in and of itself. Medicare is now seeking to broaden beneficiary choices among delivery systems as well as to preserve patients' market decisionmaking within the confines of more restrictive but higher efficiency systems. A single-winner outcome would tend to undermine these patient prerogatives.

Medicare's decision on the number of suppliers should also take into account the industry's long-term viability. As the largest single payer of health services, Medicare is perceived to have market power capable of altering the fundamental structure of health industries. To the extent that scale-related efficiencies mean lower bids, competitive bidding payment policies might be perceived as favoring large, well-financed producers, to the detriment of small ones with fewer financial resources. More so than with other payers, the long-term impact of a decision by Medicare to restrict the number of suppliers could be to reinforce a pre-existing trend toward increasing concentration—a trend now evident in numerous industries, including laboratories (Pearlstein, 1995; Hoerger et al., 1997). Given the laboratory industry's relatively low cost of entry, such an effect is likely to be short-lived (Mennemeyer et al., 1987). Nevertheless, adopting multiple suppliers is conservative, given possible concern that industries could be pushed further in the direction of concentration.

Aside from such policy considerations, sociopolitical realities also tend to favor a non-exclusive arrangement. It is widely believed that government spending should benefit not only the populations served but also the producers of services. A sharp reduction in suppliers under competitive bidding might be seen as politically and socially damaging.

A multiple-supplier bidding outcome can be varied in accordance with the weight Medicare places on savings incentives. In one variation, Medicare can exclude high bidders from supplier status, and rely on competition among those remaining—the winning bidders—to promote quality, public acceptance, and other values. In another variation, Medicare can maintain an open list of suppliers by admitting even high-

[6] Routine tests currently cost Medicare about $10 each, and very few exceed $25.

bidding firms to the market. Admitting this segment upholds another important value historically associated with Medicare, freedom of choice. Maintaining an open list of suppliers may also mitigate concerns about competitive bidding's impact on industry structure.

Obviously, admitting high bidders threatens to nullify incentives to bid aggressively. To restore these incentives, at least in part, Medicare must pay high-bidding firms prices below those paid the winning firms.[7] This approach can free up market share for the winners in two ways (Hoerger and Waters, 1993). Providers whose costs exceed the final price will tend to leave the market, thereby allowing winners to increase their volume and earn higher profits. Providers left with lower margins will tend to reduce their marketing expenditures, again with advantageous results for winning suppliers in terms of higher profits and market share.

Other Bidding Incentives

Assuming that in some instances Medicare competitive bidding arrangements adopt multiple winners and allow high-bidding firms to continue in the market, Medicare can institute incentives for attractive bids through another mechanism—the method of finding prices from the winning bids. The method has significance in terms of fostering an incentive to bid marginal cost. Because the purpose of Medicare competitive bidding is to set market-based prices, an incentive to bid marginal cost is preferred. Hoerger and Waters (1993) show that mechanisms that weaken the relationship between the firm's bid and the price received if the firm wins can increase firms' incentives to bid fees close to their marginal cost. These authors also show that if a laboratory's bid does not directly determine the price it receives, the laboratory's optimal strategy will be to set its bid equal to marginal cost.

Medicare can also build in incentives to counteract threats to access under competitive bidding—a particularly prominent issue for Medicare because of its disproportionately large rural and sick enrolled population and its social-contract origins. Access concerns arise whenever price pressures impinge on suppliers, as could occur under competitive bidding. For example, rural areas and inner cities often cost suppliers more to serve, because of factors such as smaller scale of production and greater complexity of patient needs. For laboratory services, rural areas are often problematic. Longer travel distances to collect specimens from physicians, patients, or drawing stations mean higher production costs. Local rural providers may not all be price-competitive. To provide incentives for winners to serve these areas, the volume and geographic coverage offered by the laboratory can be explicitly introduced into the bid evaluation along with the bid prices[8] (Hoerger, Eggleston, and Lindrooth, 1997).

Unit and Scope of Bidding

Another decision facing buyers in conducting competitive bidding is the unit and scope of bidding. With laboratory tests, for example, the unit may be a covered life or a procedure. HCFA is now focusing on pricing for specific procedures with the intent of testing bidding in the FFS sector. Regarding scope, limiting bidding to one or a few specific procedures in a service

[7] To realize the benefits of market-based competition, the new fee schedule would be derived from the prices offered by the winning bidders (Mennemeyer et al., 1987). Fees for the high-bidding firms could be pegged to the new fee schedule but with some discount. Medicare may also make other distinctions in favor of the low-bidding firms, such as labeling them "preferred providers" and listing them as such in informational materials.

[8] Alternatively, if the resulting bids are judged too high after incorporating rural costs, these areas can be carved out for payment under administratively based pricing.

category limits the savings potential, although this effect may be mitigated by targeting high-cost, high-profit procedures. Expanding bidding to broader sets of services should produce more savings. Also, if the outputs within a category are jointly produced so that economies of scope are possible, then excluding certain procedures within the category might be counterproductive. It could distort pricing and production decisions for the carved-out procedures.

Bidding for multiple procedures introduces additional complexity into the process. Typically, a single system of weights derived from expected service frequencies is used to average a bidder's offered prices for comparison with other bids. Bidding for multiple procedures may induce bidders to game the bidding—typically by bidding low prices for procedures that have a low expected demand for that bidder relative to the weights used for averaging. This is called "unbalanced bidding." Although this strategy can result in higher profits for the bidder and improve its probability of winning, it interferes with marginal-cost bidding. Another consequence may be a perception that some firms are unfairly advantaged simply because of the market niche they happen to occupy. In this instance Medicare, as an impartial government bureaucracy, faces unusual pressures to correct the potential inequity—pressures that private buyers can more safely ignore.

Unbalanced bidding is more likely to the extent that the provider can ensure its individualized distribution of procedures—perhaps by placing marketing emphasis on the more profitable procedure. Not all health services are separately marketable in this way. For example, within certain broad categories of laboratory tests, physicians are probably unwilling to split their orders on behalf of a single patient among multiple laboratories. Thus, one way to prevent unbalanced bidding would be to conduct separate bidding competitions for families of procedures with economies of scope in production and/or marketing. However, a major drawback of separate competitions is reduced administrative simplicity, especially in industries—such as clinical laboratories—that contain many firms offering a broad spectrum of services. Separate competitions could lead to different groups of suppliers for the various families of services. Given the frequency of Medicare transactions in the market, the result could be a confusing multiplicity of laboratory provider statuses and of fee schedules for market participants to use, maintain, and disseminate. A second option is to evaluate bids for the presence of unbalanced bidding and use that information in selecting winners. For example, possible unbalanced bidding strategies may be identified by comparing the laboratory's composite bid calculated using the competition's weights to a composite bid calculated using a set of weights based on actual historical data on the laboratory's distribution of tests.

Exemptions from Bidding

One remaining practical issue is whether to require all providers to bid. Normally only providers who bid are eligible to win or, in an arrangement admitting high bidders, are eligible to receive payment at all. Intuitively, this ensures more competition in bidding, leading to lower prices. These considerations should be weighed against the overall cost of conducting bidding. If, as with laboratory services, the health care industry is heterogeneous, with many different sizes of suppliers, then focusing bidding on the larger providers limits the total industrywide costs of preparing bids, while diluting the

cost impact. This is because, for larger providers, the fixed cost of bidding can be spread among larger numbers of services. At the same time, competition at the level of larger providers can be strong and potentially result in low prices. Because large producers may be presumed to have lower marginal costs, if they tie their bids to marginal costs, then Medicare's resulting prices will be pegged to the costs of an efficient industry segment (Pauly et al., 1991).

The extent to which smaller producers will find the resulting prices unprofitable, causing market exit and straining access, cannot be predicted in advance. Some providers may decide to continue laboratory services even if the services—viewed alone—become unprofitable.[9] Medicare can reduce access impacts of market exit either by setting conditions for winner participation that ensure supply to the market—for example, by establishing minimum volume commitments to require of bidders—or by giving additional weight in bid evaluation to access-related components of the bid—such as the volume of services offered and the geographic coverage offered.

An additional consideration for buyers is the administrative burden of evaluating a multitude of bids. If the number of bids is limited, this cost in time and resources is obviously lower. For Medicare, a national program operating in a large number of markets, limiting the number of bids for cost-saving purposes alone may prove highly attractive if competitive bidding is adopted across those markets or some subset of them. Finally, to help address equity concerns that arise when exempting some providers from bidding (i.e., non-bidders that avoid bidding risks may be unfairly positioned for rapid growth), the buyer can adopt a volume ceiling for those providers for the duration of the pricing period. This may induce bidding from otherwise exempt providers who expect to grow.

[9] For example, physicians who perceive a competitive advantage from conducting tests in their offices may decide to continue testing even if their laboratory operations—taken separately—become unprofitable.

Suitability of Laboratory Services for Bidding

In this section, we have touched on several considerations in favor of paying for Medicare laboratory services under a competitive-bidding scheme. First, we noted that it is relatively easy to observe and control key quality attributes of numerous laboratory services. Many common tests are highly automated and standardized. Moreover, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) expanded the reach of national regulation. Since passage of CLIA, all laboratories handling human test specimens must be CLIA-certified (or CLIA-waived if testing is not complex). As a result, generally accepted levels of analytic test quality are assumed to pre-exist among the providers in the market. Given the current regulatory and technological environment, which is unlikely to regress, competitive bidding would not be expected to affect significantly this aspect of quality. If it does, then regulatory structures in place should detect this quickly. Moreover, to the extent that some tests are more vulnerable to operator variation (e.g., Pap smears), these procedures can be excluded from bidding.[10] Other aspects of quality, primarily pre-analytic (e.g., courier reliability) and post-analytic (e.g., reporting timeliness) would be relatively easy to specify, incorporate in the bidder requirements, and monitor. Second, regarding the vulnerability of bidding to gaming, we noted that laboratories generally are not in a good position to fragment their major product lines for marketing purposes.

[10] This selective approach, however, may have its limitations in terms of the unit and scope of bidding.

Two additional factors favor selecting laboratory services for competitive bidding. First, the industry's organization and modes of operation indicate that entry is relatively easy. As our data below suggest, numerous entities of various types provide laboratory services, and significant numbers of these are sizable. Within certain limits, functional barriers to firms' expansion into new markets are mild. In general, skilled labor and capital requirements are not extremely demanding. These characteristics suggest that bidding competitions will attract new contestants if the winners of previous competitions are being paid too much. Second, under FFS payment, cream-skimming of low-cost patients by providers is not a concern, to the extent that cream-skimming opportunities result from health-status differences; with laboratory tests, the patient's health status seldom affects the cost of a laboratory procedure.[11]

A less favorable factor is that, unless Medicare opts for highly exclusive bidding outcomes, volume guarantees to reinforce incentives for low bids are not possible. Short of exclusive-winner arrangements, it seems unlikely that Medicare could do much to influence service allocation. Ordinarily changes in beneficiary liability offer a possible mechanism; through copayments and deductibles, preferential coinsurance rates for winning bidders could be used to influence beneficiary choice. But current payment law exempts beneficiaries from liability for laboratory services.

The conservative, multiple-winner bidding scheme we described implies certain conditions for successfully mounting Medicare competitive bidding. First, Medicare needs enough contestants to present a realistic threat that, given its intention to name multiple winners, some will be disadvantaged by bidding too high. Obviously, a competition among a handful of firms would not meet this condition, for even if price-competitive firms clearly emerged, they might be too few to guarantee post-bidding competition on quality. Second, the industry should not be experiencing serious financial difficulties, given Medicare's potentially significant impact on industrial organization.

Third, if the industry is very heterogeneous, with firms highly variable in size or experience or some other economic or social characteristic, Medicare might have difficulty conducting a competition perceived as equitable. Laboratory services are provided by differing sizes and types of firms, ranging from large multinational companies to small rural hospitals and solo physician offices.[12] Whether Medicare should be concerned about laboratories' perceptions of equity is arguable. If current laboratory fees are too high, efficiently managed laboratories are earning positive economic profits, and inefficient laboratories may be supplying Medicare. Thus, it is possible that the current fee schedule may be a source of some of the heterogeneity of firms in the laboratory industry. Under such a scenario, Medicare could improve economic efficiency by using competitive bidding to lower fees. As a result, inefficient laboratories might exit the market for Medicare services.

Despite the theoretical argument for economic efficiency, Medicare might still be concerned about laboratory perceptions of equity for pragmatic reasons. Some firms may claim that bidding imposes an unfair burden and seek relief from the obligation. They may even demand exemption from the competitively derived prices. Remaining firms might resent being singled out to take the risk of bid-

[11] However, the location of patients with respect to the laboratory's service network, particularly rural location, could be a basis for a different type of cream-skimming based on patient accessibility.

[12] This aspect of laboratory industrial organization contrasts with durable medical equipment suppliers, which are mostly small, private, for-profit businesses.

ding. Given this situation, it may be pragmatic for HCFA to seek either a leveling principle or a characteristic that fairly differentiates firms able to bear the cost of bidding with little financial strain from firms that cannot. If not, the pressures on politically sensitive segments such as physician office laboratories (POLs) and small rural hospitals might be perceived as an unacceptable cost of the fee rationalization promised by competitive bidding.

It also follows that Medicare needs a fairly streamlined bidding process, to remain receptive to contestants of varying degrees of sophistication and experience. If Medicare imposes many complicated conditions on bidders, its attempt to realize the benefits of competitive bidding without seeming to stack the deck in favor of large, well-financed providers will not be credible. Our study of the laboratory industry revealed the extent to which these conditions could be met.

DATA AND RESEARCH METHODS

We used primarily qualitative research methods to learn about the industrial organization, general competitive status, private payment arrangements, and financial status of the laboratory industry. We used mainly quantitative analyses of Medicare claims to devise a feasible and appropriate scope of bidding and to study a potential laboratory-bidding market in detail.

The methods for the qualitative research included fact-finding interviews with laboratory industry experts; review of selected documents such as general- and trade-press articles, professional association journals, company stockholder reports, Securities and Exchange Commission filings, and government studies; tracking of government procurements for laboratory services in the *Commerce Business Daily* during a 6-month period; and attendance at several industry meetings. We conducted interviews with approximately 25 laboratory experts. The interviews typically lasted about an hour and followed an unstructured format with extensive followup questions. Questions were varied between interviews to capitalize on the specific expertise and experience of the respondent. For example, respondents in areas with high managed care penetration were asked how managed care has affected laboratories, and hospital laboratory managers were asked about hospital laboratory operations.

We include in our qualitative findings descriptive data on the U.S. laboratory industry from HCFA's 1996 Provider of Service (POS) File. For laboratories, records on the file are derived from CLIA certification applications and records of surveys. POS/CLIA provider records yield essentially a census of the industry's facilities and allow tabulations of the industry's facility base and estimated operating volumes by location, ownership, and specialties.

The quantitative research on the scope of bidding relied primarily on summaries of Medicare claims from the Part B Physician/Supplier Procedure Summary file for 1992-94. The summary record reports service volume and charges by year, procedure code, physician/supplier specialty, Medicare carrier (a proxy for geographic area), and several other administrative variables. These data were used for examining the national distribution of allowed charges by laboratory test procedure to select tests for bidding. For the most common tests, we compared test-procedure rankings over time to analyze the stability of the test mix. Further, we compared test mixes among carrier areas, using as our measure of test mix the fraction of allowed charges associated with tests proposed for bidding. The results helped us assess generalizability of the bidding project from a single geographic area in time.

The detailed analysis of a market area used 1994 Tennessee National Claims History claims from Medicare Part B physicians and suppliers, and from hospital outpatient departments (HOPDs).[13] We selected claims for analysis if the test referral originated with a Tennessee physician or, in the case of hospital claims, if the test was performed by a Tennessee hospital. For this analysis we created firm-level summaries of Medicare laboratory services by linking claims with the POS/CLIA file containing firm names. The firm-level summaries were the building block for examining the industry composition, market shares, test mixes, and other characteristics reported later. A similar analysis was performed on North Carolina laboratory services claims with less extensive examination of HOPD services. In Technical Note A, we present further information on the definitions used for variable construction and on the linking variables.

FINDINGS

Qualitative Findings on Laboratory Industry Conditions

Industrial Organization

The POS/CLIA file provided descriptive data illustrating the breadth and heterogeneity of the U.S. laboratory industry. There is a POS/CLIA record for each laboratory facility. Record counts from the file showed that there were 157,793 laboratory facilities in 1996, classifiable into one of four major types: hospital laboratories, independent laboratories, POLs, and other laboratories.[14] There were 8,896 hospital-based laboratories in the country, accounting for only 5.6 percent of laboratory facilities but more than one-half of the testing volume (Figure 1). Data from a proprietary source on hospital and integrated health system laboratories suggest that about 60 percent of hospital volume is inpatient testing (Portugal, 1996). Data for 100 percent of claims from Tennessee and North Carolina suggest that slightly less than one-half of the remaining hospital activity is non-patient (i.e., for patients not seen by the hospital), as opposed to outpatient testing.

A total of 5,798 independent laboratory facilities were in operation, about 3.7 percent of the total, but the number of laboratory firms is much smaller. For example, the 10 largest independent laboratory companies account for 1,540 CLIA-certified facilities. The share of test volume for this sector is about one-quarter. Independent laboratories receive specimens on referral from physicians and transport the specimens to central facilities, where large batches of tests can be processed efficiently.

POLs were the most common type of laboratory, numbering 89,769 units and accounting for more than one-half of the facilities. The average POL is relatively small. POLs accounted for only 9 percent of the test volume, with an average annual volume per unit of only 5,800 tests. POLs typically serve their physician-owner's practice and are designed to provide quick and convenient test results. Most POLs perform a limited menu of low- or moderate-complexity tests, sending out specimens to hospital or independent laboratories for more complex procedures. Laboratories in the category "other" accounted for one-third of the facilities and resemble POLs in their volume and test mix.

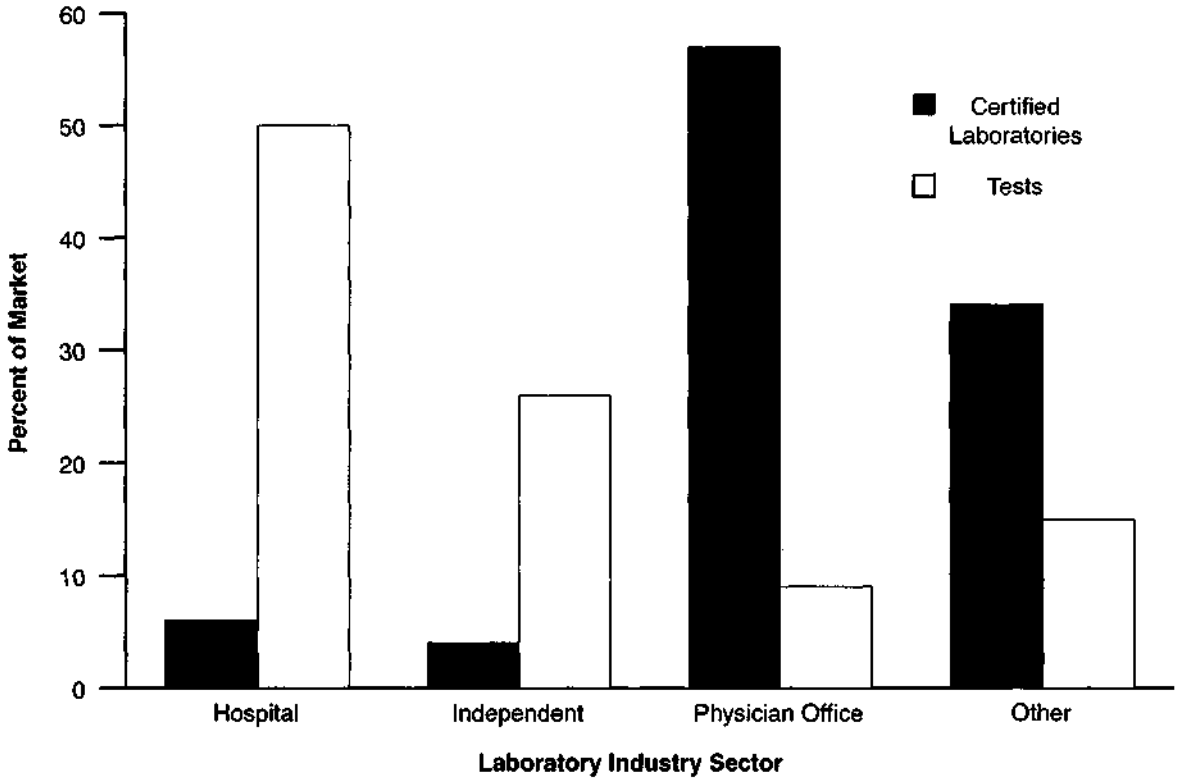
Although the small scale of production in many POLs may suggest that unit costs are relatively high, a recent study of 100

[13] Tennessee was selected under the assumption that it is a viable candidate for siting the project, pending a final decision later.

[14] The residual category, "other," includes laboratories in a wide variety of settings, such as ambulatory surgery centers, community clinics, home health agencies, health maintenance organizations, insurance companies, health fairs, and so on.

Figure 1

Comparison of U.S. Laboratory Market Shares of Facilities and Tests: 1996



SOURCE: Health Care Financing Administration: 1996 Provider of Service File.

POLs found that profits were usually good and cost was surprisingly low—in many cases below that of small community hospitals and in some cases comparable to large regional laboratories (Root, 1996; Root, undated). Similarly, some industry sources told us POL costs are not necessarily high, despite common understanding to the contrary.

A significant recent development in laboratory industrial organization has been a move to form networks, fostered largely by managed care incentives. Networks position local providers to compete for large-area MCO contracts. Definitive data on network frequency do not exist, but a recent survey suggests it is growing. The survey, of members of the Clinical Laboratory Management Association (CLMA), drew responses mostly from hospital laboratory managers. It found that 29 percent were involved in networking in 1995, and a considerably higher percent believed they would be involved in such an arrangement in 1996 (Pomerantz and LoSciuto, 1996).

Accompanying networking has been downsizing and facility consolidation, driven by the need to meet buyer demands for lower cost services. Some laboratory experts believe there is an excess of laboratory facilities and, within them, an excess of capacity. Industry consultants advise their clients to streamline by such methods as decommissioning rarely used backup equipment, joining purchasing cooperatives, introducing flexible staffing, and

culling test menus of marginally useful tests. One-half of the CLMA survey respondents engaged in downsizing in 1995. Typically, consolidation involves a multilaboratory system rationalizing production by eliminating duplication, centralizing batch testing to improve economies of scale, and specializing facilities to serve quick-turnaround or other needs.

Competitive Environment

Since 1990 there has been substantial ownership consolidation in the independent laboratory sector. By 1996 large mergers and acquisitions left three national firms dominant,[15] with an estimated 57 percent of the independent laboratory market, whereas a trade publication estimated that the top eight firms accounted for 47 percent in 1989 (Southwick, 1990). According to news reports, reasons for the mergers include economies of scale, cost savings from eliminating duplicated services in common areas, expansion into new markets, and acquisition of new technology. National-firm size rankings derived from the POS/CLIA file are fairly close to the rankings in trade reports (Hoerger et al., 1997).

To examine the implications of these findings for market concentration on a subnational basis, we analyzed State-level concentration in nine States from the POS/CLIA file, under the assumption that competitive bidding could be feasibly conducted in statewide markets. By linking multiple facility records for a single firm, firm-level volume estimates can be generated. We used the volume data to estimate roughly the market shares of independent laboratories with at least 1 percent of the volume in a State. In addition to studying the extent of industry consolidation, this analysis also served to assess the candidacies of two States, Tennessee and North Carolina, as competitive bidding project sites.

It is common for laboratory specimens to be transported across State lines for testing. Thus, these results on State market shares are treated with caution, because data based on facility location do not necessarily correspond to data based on a firm's market service area.[16] A State-by-State claims analysis would better define market shares based on actual service area and would isolate Medicare market shares specifically, but such an effort is prohibitively expensive.

The results suggested that the independent sector can be quite concentrated in some States. The shares of independent laboratory tests for the single dominant laboratories in Alabama, Georgia, Kentucky, North Carolina, and Virginia all exceeded 65 percent. By comparison, markets in Arkansas, Missouri, Mississippi, and Tennessee appeared more competitive. The three largest national laboratory companies had a notable market share in each State. At least one of the three largest firms had the highest or second-highest share in each State. However, regional independent laboratory companies had sizable market shares in Alabama, Arkansas, Mississippi, Tennessee, and Virginia. When all sectors of the laboratory industry were considered, the concentrations appeared much lower. In Tennessee, for example, the market share of the leading independent laboratory equaled 29.6 percent of independent laboratory tests but only 6.6 percent of all tests in the State, including inpatient tests. In North

[15] The dominant laboratories are SmithKline Beecham, Laboratory Corporation of America, and Quest Diagnostics, formerly Corning Clinical Diagnostics until it was spun off from Corning.

[16] Furthermore, when considering volume across all segments of the laboratory industry, the CLIA data do not permit isolation of the inpatient testing volumes within the hospital segment. Thus, estimates of market concentration from these data pertain to all testing, not just the ambulatory testing in which we were interested.

Carolina, the market share of the largest independent laboratory was 90.7 percent of independent testing, compared with 28.0 percent for all tests.

These results help explain why, despite the substantial merger activity and growing concentration among independent laboratories, antitrust regulators have not been concerned enough about possible anticompetitive effects to oppose the mergers. The Department of Justice's (DOJ) understanding of the industry's competitive status was revealed in a document approving the formation of a California laboratory network in 1995 (Bingaman, 1995). The DOJ recognized a pro-competitive potential for the network, because it would raise the number of bidders qualified to compete for large-area contracts. The DOJ letter also indicated that it views hospital laboratories and independent laboratories located within 30 minutes as competitors for stat tests (i.e., tests the results of which are needed as soon as possible). It sees hospitals and independent laboratories as serving significantly overlapping segments of the routine-testing market. The market for esoteric tests is considered much broader, because laboratories face significant competition for esoteric tests from other laboratories in a State and nationwide. As for POLs, the DOJ does not consider them to be serious competitors to hospital and independent laboratories.

Medicare laboratory competitive bidding is likely to involve the stat- and routine-testing markets. Claims data from Tennessee and North Carolina suggest a potentially strong role for hospitals in competitions within such markets. In 1994 hospital laboratories' allowed charges accounted for about one-third of the Part B tests. Data from these States also suggest that independents' Medicare share is between 34 and 44 percent (based on allowed charges), and POLs account for most of the remainder.

Private Payment Arrangements

Developments in the private sector suggest that in recent years managed care has helped pave the way for Medicare competitive bidding, by familiarizing laboratories with competitive auctions, by motivating them to understand their actual testing costs, and by fostering efficiencies through downward pressure on fees and on capitated rates. Further, reports of fee reductions attained under MCO competitive contracting highlight the possibility that Medicare's administered fees are in need of realignment.

For their part, at least some MCOs believe competitive bidding resulted in significantly lower laboratory payments—60 percent lower, in one instance—than would have been obtainable without it. Two interview respondents described to us two managed care bidding competitions. These competitions involved very large laboratories competing by invitation to cover, in one case, part of Tennessee's Medicaid population and, in the other case, the entire national HMO and preferred provider organization (PPO) enrollments of the firm. These competitions resulted in an exclusive contract for a single winner to provide all needed tests. In one competition, bidding was for a capitated rate, and in the other competition, capitated rates were bid for HMO plans, and fees were bid for PPO plans. The contractual arrangements also call for utilization monitoring data to be supplied by the laboratory, quality assurance provisions, and other services such as training physician office staff in specimen preparation.

The impact of managed care has been controversial from the perspective of the laboratories. For example, large-area com-

petitions highlight a serious perceived disadvantage for small- and medium-sized laboratories. Although networks, joint ventures, and other such arrangements are possible solutions to this problem, some laboratories appear unsure of how to operate in the zone between independence and affiliation, partly for fear of antitrust violations.

Industry Financial Status

At this writing, the recent financial performance of the large national laboratories has been poor. The "Big Three" national laboratories recently posted losses or reduced margins. A large California firm declared bankruptcy in 1996. The financial difficulties appear to be the result of the combined effects of declining fees, including Medicare and Medicaid payments; the after-effects of the mergers, which were costly and incurred large debts; and overly aggressive pricing in competing for MCO laboratory contracts. Many observers believe the larger laboratories miscalculated the benefits of aggressive bidding for MCO clients. So-called "pull-through" business—in which the laboratory, in the course of servicing MCO physicians, is able to generate testing volume from their non-MCO patients—apparently has not materialized, perhaps because much of the typical physician's caseload may already be committed to using a laboratory chosen by the insurer or HMO. Some industry observers predict that firms will attempt to adjust upward their capitated payment rates and fees as current contracts expire and are replaced with new ones.

Scope of Bidding

An issue central to the conduct of competitive bidding concerns the scope of bidding. In studying which tests might be appropriate for competitive bidding, we considered the criteria mentioned earlier. These included parsimony, test standardization, economies of scope, substitution, and test-list stability across time and space.

For this analysis we used the Physician/Supplier Procedure Summary file for 1992-94. The claims summaries exclude outpatient hospital laboratory services. Hospital-test bills are not routinely summarized by HCFA. However, to partially validate the results, we compared the Tennessee 1994 hospital test mix with the State and national physician/supplier test mix.[17]

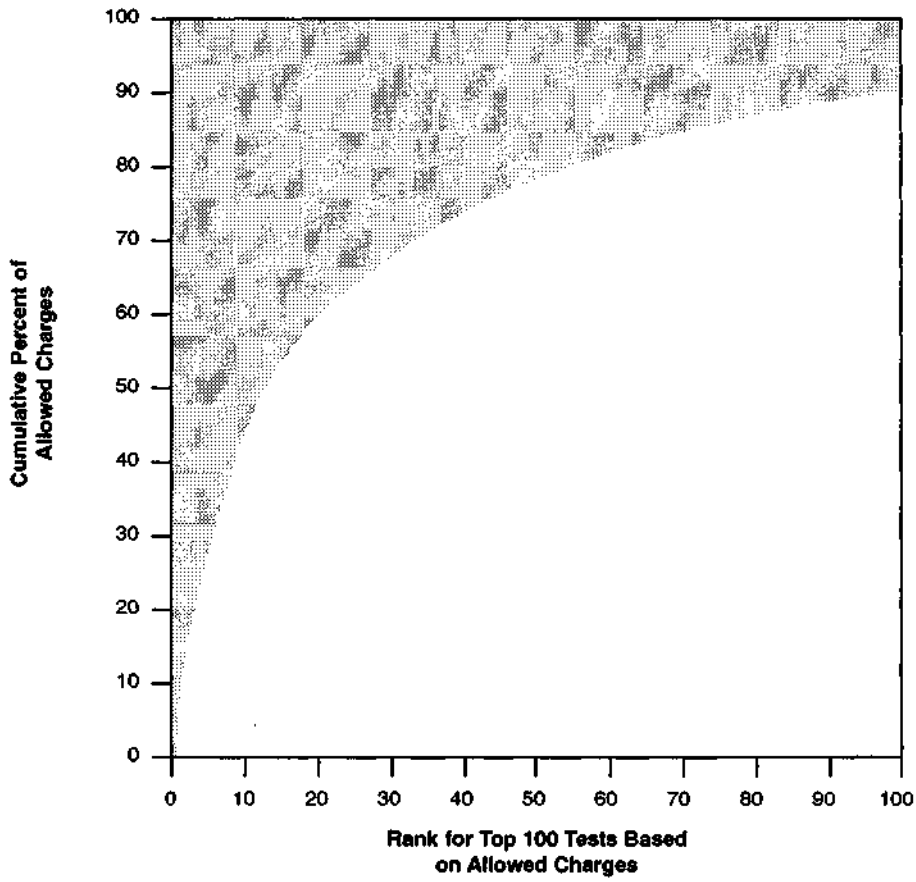
Figure 2 illustrates the concentration of Medicare laboratory allowed charges among a relatively small number of procedure codes in 1994. The top 25 tests account for 63 percent of the charges, the top 50 procedures for 78 percent, the top 75 for 86 percent, and the top 100 for 90 percent. Table 1 shows the top 25 laboratory procedures ranked by allowed charges. The most common test, an automated multichannel profile of 19 clinical chemistry tests, accounted for $254.4 million paid by Part B carriers, or 8.6 percent of the allowed charges. Volume rankings were similar to the charge rankings.

The list of common laboratory procedures has remained fairly constant in recent years. Nineteen blood/urine tests and automated hemograms ranked as the first and second most common procedures throughout the 1992-94 period. Seven of the top 10 procedures in 1994 ranked in the top 11 procedures in each of the previous years. Of the top 100 procedures in 1994, 68 were in the top 100 in the 2 preceding

[17] We generated the test mixes for Tennessee hospital laboratories and all other Tennessee laboratories from the Tennessee claims. The national test-mix data came from the Part B Physician/Supplier Procedure Summary file. The comparisons showed that the distribution of hospital laboratory procedures is similar to that for other Part B testing; the correlation coefficient of the test procedure rankings for hospital versus other Part B testing in the State was 0.67, and for hospital versus national Part B testing was 0.65 (Hoerger et al., 1997).

Figure 2

Cumulative Percent of Total Laboratory Allowed Charges by Test Rank: 1994



NOTES: Excludes clinical pathology consultations, anatomic pathology, postmortem examinations,cytogenetic studies, and surgical pathology. Includes venipuncture and trip fees.

SOURCE: Health Care Financing Administration: 1994 Physician/Supplier Procedure Summary File.

years, and of the 32 that were not in the top 100 in preceding years, 19 were ranked between 70 and 100 in 1994, where a relatively small change in allowed charges was enough to move a procedure into or out of the top 100 list.

The list of the top 100 high-expenditure tests includes some procedures in cytopathology (e.g., Pap smears), microbiology (e.g., cultures), and other areas (e.g., cell marker study) that are not automated, are more complex, or require significant interpretation. In keeping with concerns that, under price competition, such tests may be more vulnerable to quality losses than standardized ones, these were dropped from the recommended list of procedures for bidding. The technologies used to perform the omitted tests frequently differ from those used for the included tests, implying that the proposed list does not seriously violate the criterion of economies of scope. We also made some additions to the list, including several tests that ranked below the top 100, where they were potential substitutes for more commonly coded procedures.[18] In some cases these additions to the list also addressed

[18] Consultants to the project reviewed claims summaries to identify for inclusion other automated tests not requiring pretreatment that historically have been done in large numbers in independent laboratories and/or POLs, as well as automated tests, even if requiring pretreatment, that have been done in large numbers in POLs.

the scope-economies criterion. In Technical Note B, we present the resulting list, which is comprised almost exclusively of tests from two laboratory disciplines, clinical chemistry and hematology. Nationally, the proposed tests accounted for 83 percent of the carrier-paid allowed charges, and 88 percent of the test volume in 1994.

To consider list stability geographically, we compared the carrier jurisdictions (usually States) in terms of the fraction of allowed charges represented by the test procedures proposed for bidding (Hoerger et al., 1997). This subset of procedures accounted for at least 70 percent of the allowed charges in every carrier jurisdiction and topped 80 percent in all but six jurisdictions. The test volume for the subset ranged from 81 to 93 percent. Thus, the data showed relatively little variation in the listed tests' share of charges. In addition, we reviewed the detailed procedure rankings for Tennessee and North Carolina.[19] The results showed that test procedures proposed for bidding accounted for 86 percent and 88 percent, respectively, of allowed laboratory charges, and the rankings for individual procedures were fairly close to the national rankings.

Detailed Analysis of a Local Market

To examine in detail the laboratory industry market in Tennessee, we tabulated the Tennessee allowed charges by laboratory industry sector and by individual laboratory firm. We computed firms' market shares from allowed charges. We classified the laboratories with high allowed-charge totals by size class and sector and arrayed these individual laboratories by market share. We examined the individual laboratories' ratio of testing proposed for bidding to total testing. We also measured the number of counties served by each laboratory, based on the county where the specimen originated.

The county location of the physician ordering testing services on behalf of the physician's patients served as the marker for the county origin of the specimen. The specimen's origin properly locates services in the locale where laboratories are serving customers and competing. Using specimen origin departs from Medicare's organization of laboratory administrative data, as well as from the current payment basis; both are organized according to laboratory location. But if HCFA is to be able to identify markets suitable for competitive bidding based on their competitive potential, the laboratory location is irrelevant. Claims from hospital laboratories, however, have no reliable identifier analogous to the ordering physician when the hospital is effectively functioning as a community laboratory taking physician referrals. To measure hospital service area, we used the patient's county of residence on the claim as a proxy for specimen origin.

Table 2 summarizes the allowed charges and market share for Tennessee laboratories paid at least $100,000 in Medicare Part B allowed charges in 1994, and Table 3 provides detailed data on the top 25 Tennessee laboratories, ranked by allowed charges. In total, we estimated that Medicare paid $66.6 million in 1994 for all Tennessee Part B specimen testing (exclusive of pathology, cytogenetic, and postmortem procedures), of which $54.8 million, or 82 percent, was spent on the subset of tests proposed for bidding. Medicare paid 118 laboratories $100,000 or more for testing Tennessee specimens in 1994. Table 2 shows the sector composition and allowed charges for five charge-based size categories of laboratories. These 118 laborato-

[19] For these State-specific analyses, the claims universes were all carrier-paid claims where the specimen was drawn within the boundaries of the State.

Table 1

Allowed Charges and Volume for Top 25 Medicare Laboratory Procedures, Ranked by Allowed Charges: 1994

Rank	HCPCS	Procedure Name	Allowed Charges		Volume	
			Dollar Amount	Percent	Number	Percent
1	80019	19 Blood/Urine Tests	$254,418,618	8.59	17,644,690	5.64
2	85025	Automated Hemogram	164,955,013	5.57	15,775,378	5.04
3	G0001	Drawing Blood for Specimen	142,936,295	4.83	50,605,064	16.18
4	80092	Thyroid Panel with Thyroid-Stimulating Hormone	117,118,714	3.95	2,935,232	0.94
5	84443	Assay Thyroid-Stimulating Hormone	112,964,524	3.81	5,065,988	1.62
6	83718	Blood Lipoprotein Assay	109,648,793	3.70	10,171,411	3.25
7	85024	Automated Hemogram	105,442,911	3.56	9,392,220	3.00
8	84153	Prostate Specific Antigen	105,377,003	3.56	4,768,813	1.52
9	80061	Lipid Panel	90,906,979	3.07	4,541,265	1.45
10	81000	Urinalysis, Non-automated with Microscopy	81,250,559	2.74	18,589,319	5.94
11	85610	Prothrombin Time	62,422,306	2.11	11,235,609	3.59
12	80162	Assay for Digoxin	59,457,910	2.01	3,171,203	1.01
13	83550	Iron Binding Test	46,626,240	1.57	4,205,972	1.34
14	87086	Urine Culture, Colony Count	42,075,766	1.42	3,911,629	1.25
15	82728	Assay Ferritin	40,075,337	1.35	2,365,578	0.76
16	80016	13-16 Blood/Urine Tests	38,495,295	1.30	2,730,400	0.87
17	83036	Glycated Hemoglobin Test	38,471,090	1.30	2,959,179	0.95
18	82947	Assay Quantitative, Glucose	36,663,590	1.24	6,849,241	2.19
19	83540	Assay Iron	35,747,533	1.21	4,255,416	1.36
20	84436	Assay, Total Thyroxine	34,712,217	1.17	3,840,047	1.23
21	85023	Automated Hemogram	34,622,548	1.17	3,015,999	0.96
22	80018	17-18 Blood/Urine Tests	32,643,684	1.10	2,338,780	0.75
23	80091	Thyroid Panel	30,796,066	1.04	1,757,267	0.56
24	80007	7 Clinical Chemistry Tests	27,307,811	0.92	2,630,911	0.84
25	82378	Carcinoembryonic Antigen	25,825,469	0.87	1,072,170	0.34

NOTE: HCPCS is Health Care Financing Administration Common Procedure Coding System.

SOURCE: Health Care Financing Administration: 1994 Physician/Supplier Procedure Summary File.

Table 2

Laboratory Part B Allowed Charges, Market Share, and Number of Laboratories, by Allowed-Charges Category: Tennessee, 1994

Allowed-Charges Category of Laboratories	Allowed Charges		Market Share		Number of Laboratories			
	All Tests	Tests for Bidding	All Tests	Tests for Bidding	IL	HL	POL	Total
			Percent					
All Laboratories Paid [1] at Least $100,000	$47,498,650	$38,694,691	71.5	70.5	15	78	25	118
$1.0 million or more	18,715,324	15,987,140	28.1	29.1	4	1	0	5
$400,000-999,999	10,817,340	8,179,745	16.2	15.0	2	14	1	17
$300,000-399,999	3,871,491	3,013,412	5.8	5.5	3	8	0	11
$200,000-299,999	4,747,985	3,984,930	7.0	7.3	0	14	5	19
$100,000-199,999	9,346,510	7,529,464	14.4	13.6	6	41	19	66

[1] Paid at least $100,000 in Medicare Part B allowed charges.

NOTES: IL is independent laboratory. HL is hospital laboratory. POL is physician office laboratory.

SOURCE: Medicare Part B Standard Analytical Files of carrier-paid and fiscal-intermediary-paid claims.

Table 3

Market Shares and Coverage Areas for the 25 Top-Ranked Laboratories, by Laboratory: Tennessee, 1994

Laboratory Designation	Type of Lab	Number of Counties Served [2]	Allowed Charges		Charges for Bid Tests as Percent of Total Charges	Market Share[1]	
			All Tests	Tests for Bidding		All Tests	Tests for Bidding
						Percent	
Total, All Laboratories			$66,649,181	$54,817,427	82	100.0	100.0
Subtotal, Top 25 Laboratories			30,681,979	25,042,060	82	46.0	45.7
All Laboratories Paid at Least $100,000			47,498,650	38,694,691	81	71.5	70.5
Lab A	I	88	6,996,255	5,882,388	84	10.5	10.7
Lab B	I	85	5,936,251	5,257,251	89	8.9	9.6
Lab C	I	54	2,800,564	2,382,849	85	4.2	4.3
Lab D	I	45	1,748,761	1,508,106	86	2.6	2.8
Lab E	H	26	1,233,493	956,546	78	1.9	1.7
Lab F	H	51	981,211	720,285	73	1.5	1.3
Lab G	H	36	980,517	605,446	62	1.5	1.1
Lab H	I	15	867,849	683,873	79	1.3	1.2
Lab I	H	78	853,607	587,886	69	1.3	1.1
Lab J	H	29	791,677	604,511	76	1.2	1.1
Lab K	H	28	676,242	571,010	84	1.0	1.0
Lab L	I	13	651,165	617,812	95	1.0	1.1
Lab M	H	13	643,804	487,049	76	1.0	0.9
Lab N	H	14	542,997	416,202	77	0.8	0.8
Lab O	H	18	538,008	442,267	82	0.8	0.8
Lab P	H	20	494,302	379,819	77	0.7	0.7
Lab Q	POL	12	482,683	448,437	93	0.7	0.8
Lab R	H	48	479,453	359,433	75	0.7	0.7
Lab S	H	17	479,407	312,403	65	0.7	0.6
Lab T	H	26	478,748	368,269	77	0.7	0.7
Lab U	H	12	454,274	265,186	58	0.7	0.5
Lab V	H	29	421,396	309,857	74	0.6	0.6
Lab W	H	17	393,280	276,090	70	0.6	0.5
Lab X	I	8	385,718	317,617	82	0.6	0.6
Lab Y	H	23	370,317	281,468	76	0.6	0.5

[1] Computed from allowed charges.

[2] Number of counties served for hospital laboratories based on proxy measure; see text for details.

NOTES: I is independent. H is hospital. POL is physician office laboratory.

SOURCE: Medicare Part B Standard Analytical Files of carrier-paid and fiscal-intermediary-paid claims.

ries accounted for about 72 percent of the market for all Tennessee testing as well as 71 percent of the market for the tests proposed for bidding. Hospital laboratories predominate; 78 of the 118 laboratories were hospital-based. Twenty-five of the laboratories were POLs, and 15 were independent laboratories.

The largest size category had charges totaling $18.7 million. This category was composed of four independent laboratories and a single hospital laboratory network, each with at least $1 million in allowed charges. Charges for tests proposed for bidding were $16.0 million. These five laboratories accounted for 28 percent of the Tennessee Part B testing market, and a similar percent of the market for tests proposed for bidding. In the remaining size categories, hospital laboratories predominate. The second-largest category, laboratories billing from $400,000 to $999,999, contains 17 laboratories having a total market share of about 16 percent. Only one POL is large enough to fall into this size range. The next two categories were $300,000-399,999 and $200,000-299,999. With 11 and 19 laboratories, respectively, each category accounts for about 6-7 percent of the allowed charges. The POLs tend to cluster in the smallest class, $100,000-199,999.

Table 3 provides a more detailed look at the largest laboratories. The allowed charges and market shares of these laboratories varied markedly. Although we do not identify the laboratories in Table 3, we note that the three largest national laboratories accounted for the top three Part B Medicare market shares in Tennessee. These three firms had a combined share of about 24 percent, and their payments ranged from $2.8 million to $7.0 million. Ten other laboratories had market shares of about 1 percent or higher. Hospital and independent laboratories each accounted for one-half of the top 10 laboratories in payments, although independent laboratories tended to cluster in the upper half of the top 10.

Table 3 also shows the charges for tests proposed for bidding as a percent of total testing charges and the number of counties served by each laboratory. The percent ranged between 58 percent (one hospital laboratory) and 95 percent (one independent laboratory), with four-fifths of the firms exceeding 70 percent. Based on data from independent and physician office laboratories, breadth of service area roughly paralleled allowed charges. The two largest laboratories provided nearly statewide coverage, with one serving 88 of Tennessee's 95 counties and the other serving 85. The next two laboratories served about one-half of the counties. After that, only two other laboratories—one POL and one independent—served at least one-third of the counties in the State (data not shown). The specimen-origin proxy data suggest that at least three hospitals achieved coverage comparable to some of the largest independent laboratories, as measured by the number of counties served. Several other hospitals appear to have served at least one-quarter of the counties. However, no hospitals apparently provide statewide coverage.

We associated each county with a count of independent, hospital, and POLs serving it in 1994. The results suggested that the number of such laboratories serving a county and the share of county payments due to independent laboratories varied widely. Unsurprisingly, the number of providers was closely related to allowed charges. Rural counties—which account for about two-thirds of Tennessee counties—generally had low allowed charges, and were served by fewer laboratories of all types than urban counties. Fifteen counties were served by only one independent

laboratory and, of these, five were served by only one POL. Thirteen of the 15 counties were rural. Almost all counties had at least one hospital laboratory physically present, and hospitals appeared to have large market shares in many rural counties. The data also suggest that rural beneficiaries often have laboratory tests drawn in urban counties, even when laboratory services are available in their own counties. This result is consistent with findings for other health services (Bronstein and Morrisey, 1990).

DISCUSSION

In this article we have described clinical laboratory industrial organization and the industry's current competitive and financial status; delineated an appropriate scope for laboratory competitive bidding; and portrayed a local Medicare laboratory market. For most areas of inquiry, no single source of information can provide a precise answer. Some of the available data were impressionistic, gathered from industry experts. Thus, we relied on multiple sources, and we qualified our conclusions in the text as necessary.

The qualitative findings suggested that, notwithstanding recent indications of increased concentration in the independent sector, the industry remains competitive. Hospital laboratories have a greater market share than we initially expected, and may be generally viewed as capable of providing price competition leading to lower Medicare fees. Large POLs may occasionally enlarge the pool of presumptive bidders. Moreover, firms need not necessarily feel constrained by concerns about antitrust violations. Extrapolating the DOJ antitrust framework to a Medicare competitive bidding scenario, it seems that in many areas there is an opportunity for laboratories, especially small- and medium-size ones, to affiliate to bid and deliver Medicare tests, without adversely affecting the longer term price-competitiveness of the local market. This may mean opportunities for firms to enhance their attractiveness as Medicare bidders on non-price dimensions such as rural coverage.

Our POS/CLIA file analysis of independent laboratory concentration suggested that not all local environments would be equally suited for mounting bidding pilots or policies. In our study we found that Tennessee's laboratory services market appears to be among the more competitive ones in its region. In contrast, another State market, North Carolina, was more dominated by independent laboratories and exhibited more concentration in the independent laboratory sector.

The recent financial difficulties of the largest national laboratories and the evidence of significant organizational restructuring do not in our view preclude testing Medicare competitive bidding for laboratories. Some industry participants think these developments are evidence that the industry structure will change from one dominated by national behemoths to one in which regional firms and networks of hospital laboratories or others hold sway over the routine-testing market in more localized areas. If this is so, then the routine-testing market may offer continuing opportunities for purchasers, including Medicare, to use market rivalries to obtain lower prices and better service. Similarly, to the extent that trends to consolidate and downsize have lowered laboratories' production costs, these trends may be positioning many providers favorably for the advent of Medicare competitive bidding. It is possible, however, that the financial difficulties, associated too with an overall tightening of payment policies by Medicare and other payers, may presage limited potential for additional Medicare savings. Even so,

we believe Medicare may well benefit from a reordering of fees, if not a general price reduction. It should also be noted that most other sectors of the health care system have been undergoing major restructuring, but this has not dissuaded private and public insurers from seeking additional payment reform.

Our study of test procedures to put up for bidding found a highly skewed distribution of allowed charges by test. This implies that some of the complexity of bidding for the full spectrum of nearly 900 different laboratory procedures can be reduced by limiting the scope to the most common tests. For Medicare, this parsimony seems attractive. Unlike the two large-area, invited managed care competitions that covered all tests, Medicare may find it prudent to have as open a competition as possible, consistent with overall cost efficiency, for reasons of quality and public acceptance discussed earlier. This is facilitated by a simpler bidding procedure. Streamlining the test list will have little effect on potential cost savings, because the bulk of laboratory allowed charges will still be covered.

The State comparisons of test mix, as well as the comparison of the national test ranking against rankings for Tennessee and North Carolina, suggested that essentially the same set of tests could be used, perhaps with slight State-specific modification, no matter where the laboratory bidding is conducted. If Medicare were to use several competitions for benchmarking a programwide fee schedule, both the time- and space-related stability of the test list offer some evidence that the bidding results are generalizable.

Our findings from the claims-based study of Tennessee laboratory firms illustrate that, at least at the statewide level, it is possible to have a sizable group of providers from the three major sectors of the industry as apparently viable contestants for Medicare competitive bidding. The very largest laboratories are independent laboratories, but hospital laboratories are more common in the top 25 and among the entire list of laboratories paid $100,000 or more. It appears that HCFA can expect to obtain bids from reasonable numbers of both hospital and independent laboratories—laboratories that account for a substantial share of all Part B specimen testing—if it requires the largest laboratories to bid and if it is willing to evaluate at least 20 bids. The few POLs that rival hospital and independent laboratories in charges can be included as bidders to broaden laboratory representation and generate market information from the POL sector. In contrast to the Tennessee results, the data from North Carolina indicate that markets in some States may be fairly concentrated, at least in the independent laboratory sector. Thus, the results from the two State studies underline the importance of carefully selecting sites for bidding competitions.

The results of the State studies may also mean that where laboratory market structures resemble Tennessee's, Medicare for the most part can sidestep the politically sensitive question of POL participation in the bidding. With few exceptions, the POLs in Tennessee rank among the small laboratories for whom we assume bidding costs are not justifiable. This finding may be generalizable to other areas of the United States. As for the impact of competitively derived prices on POLs, that remains to be seen. Although the limited data available on POL costs suggests many POLs are profitable, expert opinion on the likely impact of competitive pricing is mixed. Some experts told us POLs would not necessarily be disadvantaged by pricing outcomes of Medicare competitive bidding, but others strongly disagreed.

Another implication of the Tennessee study is that requiring laboratories to provide statewide or large-regional coverage is probably not a desirable objective in all potential Medicare bidding arrangements, notwithstanding the examples of large-area contracts in the private sector. Very few laboratories approached statewide coverage in Tennessee. If such large-area coverage were required, most laboratories would probably have to form alliances to participate. Their general uncertainty about the antitrust implications may dampen this response, and Medicare may wish to avoid requirements with strong structural implications. Moreover, with multiple winners there is little reason to require any single laboratory to provide statewide coverage as long as the winners collectively provide it.

The Balanced Budget Act calls for testing competitive bidding in metropolitan statistical areas (MSAs) or sub-MSA areas, rather than statewide areas. Mounting the demonstration in MSAs would ease potential concerns about access arising from the low number of laboratories serving some rural counties. However, future planners of broader competitions should anticipate possible difficulties in finding price-competitive firms to serve some rural areas.

In conclusion, characteristics of laboratory services per se augur well for deriving market-based prices within the Medicare program. The scope of bidding can be narrowed to suit Medicare's needs while capturing the great bulk of laboratory expenditures. Private sector arrangements have laid some groundwork for Medicare to adopt its own brand of competition. Our research also revealed conditions in today's laboratory industry that can complicate Medicare's effort to add competitive bidding to its repertoire of payment approaches. The complicating conditions include the variable industry concentration across geographic markets, social and economic heterogeneity among the firms themselves, heightened sensitivity to antitrust issues, and indications of uneven financial health across the industry. As with other health care services, the problems posed by laboratory operations in rural areas highlight the issue of the policy's impact on access to care. Bidding-scheme design options are available to address various conditions, such as those relating to firm heterogeneity and beneficiary access. Careful selection of bidding markets can further enhance Medicare's chances of achieving lower priced, high-quality, and accessible services through market competition.

ACKNOWLEDGMENTS

The authors wish to thank Philip Cotterill for editorial guidance and Teresa DeCaro, Jay Bae, and two anonymous referees for helpful comments on earlier drafts of this article. We also acknowledge Joyce Eng for explaining certain technical aspects of clinical laboratory science and Richard Lindrooth and Jennifer Eggleston for data processing assistance.

TECHNICAL NOTE A

The following definitions were used in constructing variables for the Tennessee claims analysis:

Specimen-origin identifiers: For carrier-paid claims, we used the claim ordering physician unique physician identification number (UPIN) to determine the specimen's State of origin. We obtained lists of UPINs for Tennessee and North Carolina Medicare physicians from HCFA's UPIN Registry file. The carrier code on the UPIN record was sufficient to identify all physicians practicing in each of these two States. We searched the 1994 National Claims History (NCH) Standard

Analytical File (SAF) of clinical laboratory services to collect all claims bearing these UPINs in the ordering-physician field. For fiscal-intermediary-paid claims, we searched the 1994 NCH Outpatient SAF for all outpatient laboratory services from institutional providers in Tennessee and North Carolina. The State code embedded in the provider number was used as the State identifier.

County identifiers: To approximate the county of origin for a test specimen, the UPIN record's business ZIP Code was used on carrier-processed claims. The ZIP Code was mapped to a county code. For hospital services, the hospital's county location from the Provider of Service file (linked to the claim by the provider number) was used to indicate the specimen's origin for outpatient hospital laboratory claims only. There is no ordering physician on hospital laboratory claims, making the county of origin unavailable for hospital non-patients (i.e., patients whose specimens are sent to the hospital from external sources). Consequently, for claims of hospital non-patients, we used the beneficiary county of residence to proxy the specimen origin.

Laboratory firm identifiers: We linked all CLIA numbers of a given laboratory firm, by manually matching the names on the CLIA Provider of Service File. CLIA numbers on claims were then grouped to identify all of a laboratory firm's claims.

Industry sector identifiers: Laboratory claims were aggregated by laboratory industry sector (independent; hospital; and POLs combined with "other") as well as by laboratory firm. The claim specialty code was used to identify the sector for carrier-paid claims only. For fiscal-intermediary-paid claims, the sector was assumed to be hospitals; in fact, these claims are overwhelmingly from hospitals, although other institutional claims are represented.

Non-patient claim determination: A laboratory service was assumed to be performed for a hospital non-patient if there were no service types other than laboratory on the claim. (This method was informally validated from data obtained directly from the fiscal intermediary.)

Procedure identifiers: Laboratory procedures were identified using the HCFA Common Procedure Coding System code.

Technical Note B

Preliminary List of Clinical Laboratory Tests Proposed for Bidding, Listed by Procedure Code

HCPCS Procedure Code	Description
80019-G0058	20 Clinical Chemistry Tests
80019-G0059	21 Clinical Chemistry Tests
80019-G0060	22 Clinical Chemistry Tests
G0001	Drawing Blood for Specimen
P9604	One-Way Allow Prorated Trip
P9605	Routine Venipuncture
80002	1-2 Clinical Chemistry Tests
80003	3 Clinical Chemistry Tests
80004	4 Clinical Chemistry Tests
80005	5 Clinical Chemistry Tests
80006	6 Clinical Chemistry Tests
80007	7 Clinical Chemistry Tests
80008	8 Clinical Chemistry Tests
80009	9 Clinical Chemistry Tests
80010	10 Clinical Chemistry Tests
80012	12 Clinical Chemistry Tests
80016	13-16 Blood/Urine Tests
80018	17-18 Blood/Urine Tests
80019	19 Blood/Urine Tests
80050	General Health Panel
80058	Hepatic Function Panel
80061	Lipid Panel
80091	Thyroid Panel
80092	Thyroid Panel with Thyroid-Stimulating Hormone
80162	Assay for Digoxin
80185	Assay for Phenytoin
80198	Assay for Theophylline
81000	Urinalysis, Nonautomated, with Microscopy
81002	Urinalysis, Nonautomated, Without Microscopy
81003	Urinalysis, Automated, Without Microscopy
81005	Urinalysis
81015	Microscopic Exam of Urine
82150	Assay of Amylase
82172	Apolipoprotein
82250	Assay Bilirubin
82270	Test Feces for Blood
82310	Assay Calcium
82330	Assay Calcium-Ionized
82378	Carcinoembryonic Antigen
82465	Assay Serum Cholesterol
82540	Assay Creatine
82550	Assay CK (Creatine Phosphokinase)
82565	Assay Creatinine
82570	Creatinine: Other Source
82607	Vitamin B-12
82728	Assay Ferritin
82746	Blood Folic Acid Serum
82784	Assay Gammaglobulin IgM
82947	Assay Quantitative, Glucose
82948	Reagent Strip/Blood Glucose
82962	Glucose Blood Test
82977	Glutamyltransferase, Gamma
82985	Glycated Protein
83036	Glycated Hemoglobin Test
83520	Immunoassay, RIA (radioimmunoassay)
83540	Assay Iron
83550	Iron Binding Test
83615	Lactic Dehydrogenase
83690	Assay Lipase
83718	Blood Lipoprotein Assay (High-Density Lipoprotein)
83721	Blood Lipoprotein Assay (Low-Density Lipoprotein)
83735	Assay Magnesium
83970	Assay of Parathormone
84066	Assay Acid Phosphatase
84075	Assay Alkaline Phosphatase
84100	Assay Phosphorus

Technical Note B—Continued

Preliminary List of Clinical Laboratory Tests Proposed for Bidding, Listed by Procedure Code

HCPCS Procedure Code	Description
84132	Assay Serum Potassium
84153	Prostate Specific Antigen
84155	Assay Protein
84165	Assay Serum Proteins
84295	Assay Serum Sodium
84436	Assay, Total Thyroxine
84439	Assay, Free Thyroxine
84443	Assay Thyroid-Stimulating Hormone
84450	Transferase, Aspartate Amino
84460	Transferase, Alanine Amino
84466	Transferrin
84478	Assay Triglycerides
84479	Assay Triiodothyronine (T-3)
84520	Assay Urea Nitrogen
84550	Assay Blood Uric Acid
85007	Differential White Blood Cell Count
85013	Hematocrit-Spun
85014	Hematocrit-Other than Spun
85018	Hemoglobin
85021	Automated Hemogram
85022	Automated Hemogram
85023	Automated Hemogram
85024	Automated Hemogram
85025	Automated Hemogram
85027	Automated Hemogram
85029	Automated Hemogram
85030	Automated Hemogram
85031	Manual Hemogram, Complete Blood Count
85044	Reticulocyte Count
85048	White Blood Cell (WBC) Count
85610	Prothrombin Time
85651	Red Blood Cell Sedimentation Rate
85730	Thromboplastin Time, Partial
86255	Fluorescent Antibody Screen
86287	Hepatitis B Surface Antigen (HBsAg)
86291	Hepatitis B Surface Antibody (HBsAb)
86316	Immunoassay, Tumor Antigen
86430	Rheumatoid Factor Test
86592	Blood Serology, Qualitative

HCPCS is HCFA Common Procedure Coding System.

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