Legal Backgrounder

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IS AMERICA'S HEALTH CARE HINDERED BY "GROUP PURCHASING ORGANIZATIONS"?

by

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The relaxation of the antitrust laws, promulgation of safe harbors in Medicare's anti-kickback provisions for group purchasing organizations ("GPOs"), and concomitant concentration of market power in two dominant GPOs[1] have combined to significantly reduce competition, stifle innovation, and create barriers to market entry in the health care system. Such unintended results of these policy changes and unchecked developments in GPO market concentration have led to higher prices for medical equipment and compromised the health and safety of health care workers and their patients.

Until recently, neither Congress nor the Justice Department had stepped in to seriously investigate the effects of GPO mergers, nor the effect of GPO purchasing practices on the medical device and supply industry. The Senate's Judiciary Committee Antitrust Subcommittee has recently taken interest in the issue, and announced it would hold a hearing on April 30. This is an important step towards an eventual revisiting of the regulations and laws that gave life to the growth and consolidation of group purchasing organizations. Clearly, the current situation is not as Congress had intended.

The History of Federal Regulation of Group Purchasing Organization Joint Purchasing. In the late 1980s, experts and policymakers became concerned that large manufacturers of medical products had acquired such significant market power that they were in a position to take advantage of the relatively small hospitals and clinics that purchased these supplies by offering products only at high prices and limiting the range of available medical supply items. The remedy chosen to correct this competitive imbalance was to allow hospitals to aggregate their purchases through group purchasing organizations, collectively giving hospitals that band together countervailing market power in their negotiations with the large manufacturers. Policymakers intended for regional groups of hospitals to band together for the purposes of joint buying, and they did. In the early 1990s, there were thousands of regional GPOs.

In carrying forth this policy prescription, federal antitrust regulators at the Department of Justice established antitrust "safe harbors" for health care GPOs in 1994, immunizing their members' collective action from scrutiny under the antitrust laws. To further encourage and nurture the development of GPOs, Congress exempted them from Medicare's anti-kickback provisions, thereby allowing GPOs to collect "administrative fees" from medical product manufacturers.

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[1]The Premier and Novation GPOs together combine to provide medical supplies to nearly two-thirds of America's hospital beds.

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As part of its effort to encourage the development of GPOs, Congress passed the Medicare and Medicaid Patient and Program Protection Act of 1987. This Act specifically mandated HHS to promulgate regulations to specify various payment and business practices which, although potentially capable of inducing referrals of business under federal and state health care programs, would not be treated as criminal offenses under the federal anti-kickback statute.[2] Pub.L. 100-93, section 14

In its 1991 final rule on the anti-kickback safe harbors, the Department of Health and Human Services Office of the Inspector General (OIG) mandated a three-percent maximum administrative-fee figure. The OIG noted that the legislative history of the 1987 law "shows Congress's concern for excessive GPO fees, particularly those exceeding 3 percent," and revised the rule to require a GPO to specify the administrative fee "only if any fee will be above 3 percent." The OIG believed that this would "retain the focus on excessive fees about which Congress was concerned." 56 Fed. Reg. 35952, 35982.

GPOs Skirt the Prohibition Against High Administrative Fees. Despite congressional limitations on administrative fees charged by GPOs to manufacturers to three percent of total sales, examples abound of creative GPO fee arrangements that effectively raise the administrative cost of doing business with a GPO to a higher level. One result of these excessive fees is to effectively price some manufacturers out of being able to afford to market their products through the GPOs.

Examples of fees and charges outside the "traditional" administrative-fee structure include the following:

- Some GPOs have begun developing "private-labeling arrangements" with manufacturers, under which participating manufacturers must pay a significant licensing fee to the GPO for the ability to market their products to GPO member hospitals under the GPO's name.

- One GPO charges manufacturers up to eight percent or more of gross sales to participate in its restrictive "Spectrum" bundling baskets.

- GPOs have been known to take a financial stake in companies to which they offer a preferred contract.

Market Access Barriers to Hospitals. The unintended consequences of policy decisions and unfettered marketplace concentrations in the health care sector have led to a situation in which two large GPOs (Premier and Novation) wield such enormous market control, and exercise near exclusive access to two-thirds of the nation's hospital beds, that it is virtually impossible for medical device manufacturers to exist without a supply contract with one of these two firms.

No Incentive to Reduce Prices. One of the elemental problems with the current GPO-dominated management of hospital purchasing is that GPOs have little to gain from negotiating lower prices from their preferred vendors, since GPOs receive a flat percentage of sales, not a percentage of the "savings" they generate for their members. With this in mind, the reluctance of many GPOs to disclose how they calculate these "savings" and the limitations these GPOs place on their member hospitals' ability to entertain proposals from competing vendors who are not under GPO contracts should lead federal policymakers to question the very appropriateness of the safe harbors and the business practices they have encouraged.

Extreme Length of Exclusive Contracts Blocks Competition, Innovation. Another of the running themes of any comprehensive critique of the practices of the dominant group purchasing organizations is

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[2]Section 1128B(b) of the Social Security Act [42 U.S.C. 1320a-7b(b)] ["the anti-kickback statute"] provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the federal or state health care programs.

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the fact that their exclusive and long-term contracts with both manufacturers and hospital customers significantly reduces the introduction of innovative medical technology to the operating room. In this sort of environment, venture capital disappears and new product ideas get shelved.

GPOs claim that their long-term contracts do not exclude any manufacturer from competing for the business of their member hospitals. GPOs even tout the existence of processes for allowing member hospitals and their doctors to evaluate and use new or advanced technologies from manufacturers that are not currently under contract. In truth, however, these processes are highly convoluted and essentially toothless.

GPOs Discourage Competitive Bidding by Prohibiting Member Hospitals from Evaluating Non-Listed Products. GPOs limit the ability of manufacturers *outside* the GPO from selling products to hospitals at lower prices, thus preventing their member hospitals from even considering products from non-approved vendors, regardless of their being of superior quality or lower price.

The GPOs manage this by several methods. One GPO, for instance, has a purchasing policy that commits member hospitals to purchasing 90 percent of their needs for products from the one or two manufacturers under contract with the GPO. In essence, these contracts restrain hospitals from entertaining proposals or even comparing the prices or the quality of competing products offered by manufacturers not under contract with the GPO for the duration of their contracts.

In return for this compliance, hospitals are supposed to receive best market pricing, along with rebates, discounts, and other incentives, for complying with the product contracts arranged by the GPOs. This seems counterintuitive, however, when hospitals are not even allowed to entertain lower bids from non-GPO suppliers without jeopardizing better pricing they receive on other, unrelated products through the GPO.

Bundling and Tying. When medical device manufacturers actually do secure a contract with a major GPO, they are often subjected to a second barrier of entry to the hospital market, namely, bundling arrangements designed by the GPOs to promote certain products over others. The majority of these bundling and tying arrangements, such as the one promoted by Novation, (its so-called "Spectrum" programs), create significant incentives for hospitals to avoid purchase of certain products that are not included in the basket of preferred products, in order to avail themselves of special discounts. By linking a hospital's savings to its commitment to purchase at least 80% or 90% of its needed products from those selected as part of a Spectrum package, for example, virtually ensures that other product manufacturers that have competing products on the GPO's list of approved products can compete for no more than a 10% market share in participating hospitals. Additionally, Novation is known to charge manufacturers an additional fee for the right to participate in a Spectrum bundle above and beyond the 3% administrative fee allowable under law. In effect, this fee is paid by selected manufacturers in return for ensuring that they will enjoy the benefit of near-exclusive access to hospitals that choose to participate in the Spectrum program.

Breakthrough Technology. Premier, one of the two leading GPOs, seems to have recognized that the GPO model frustrates innovation, given that a significant amount of medical device innovation is generated by the same entrepreneurs on whom the GPOs place a myriad of administrative and contractual hurdles. To address this weakness, Premier offers a "breakthrough technology" program by which small companies with innovative technologies are supposedly given the opportunity to sell their products through the GPOs. Because of the multi-year, near-exclusive supply contracts hospitals sign with GPOs, it is virtually impossible for non-GPO selected manufacturers to sell their innovative new products to hospitals or their doctors.

Unfortunately, the Premier breakthrough technology program has proved nothing more than a

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pinhole through which only one or two new products from innovative new companies have pushed through. There are several reasons why the Premier program has failed to accommodate more than a handful of new products in over three years, including a proliferation of administrative hoops, the requirement of an unreasonably high level of innovation, high evaluation fees, and an exclusionary review process.

Electronic Commerce Adds New Concern. Premier and Novation recently teamed up with electronic medical supply companies Medibuy and Neoforma to provide medical supplies and products to member hospitals over the Internet. While there is nothing about utilizing electronic means to sell hospital supplies or products that is in and of itself improper, this new mechanism for providing GPO supplies to hospitals will allow GPOs to better police and enforce their Member hospitals' buying behavior by controlling all the information that flows from purchaser to manufacturer. Under current circumstances, hospital buyers often purchase their products and supplies directly from manufacturers. This will change as more hospitals are directed by their GPOs to utilize electronic purchasing tools run through Novation and Premier.

Because GPOs will increasingly have access to all buying information from their member hospitals, they will be able to better police their members' buying practices and more easily enforce restrictive contract terms. GPOs will thus be able to utilize this new buying data to influence the purchasing of their member hospitals to an even greater degree, making it even more difficult for non-GPO approved suppliers to participate in the health care market.

Conclusions. In addition to the changes in the health care marketplace owing to policy decisions and market concentrations, the 1990s saw shifts in the relationships and power dynamics between doctors, hospitals, GPOs, and manufacturers. Where once doctors had the ability to determine the products and devices they used in the operating room, now non-doctor hospital administrators hold the key to product purchasing and usage. Where GPOs once were nothing more than a loose affiliation of regional hospitals united for the purpose of contract bidding, now GPOs have themselves become multi-billion dollar for-profit corporations with profit motives that are often at odds with the hospitals they supposedly represent.

While there may have been good reason to provide safe harbors from antitrust law to encourage hospital group purchasing nearly a decade ago, it now appears that there is something amiss in the medical supply market. Given the questions raised by unanticipated shifts in the health care marketplace and the consolidation of group purchasing entities, as well as the unwarranted difficulties faced by medical device entrepreneurs to break into the hospital market, comprehensive inquiry by the Congress and Justice Department is warranted. GPOs, and the hospitals they are supposed to represent, should also scrutinize their own practices and come up with industry-wide suggestions for improving utilization of new technologies, improving market access for innovative new companies, and removing barriers to fair competition among all companies and products that are on contract.

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