Contractual Arrangements Between HMOs and Medical Groups to Manage Drug Costs

In the middle 1980s, a national for-profit health maintenance organization (HMO) signed pharmacies, physicians, and hospitals to full-risk (capitation) financial arrangements that left many of these contract providers bankrupt or financially devastated. Many medical and hospital providers have come to more fully appreciate that financial risk can, in fact, be very risky. Several pharmacy administrative service organizations ceased to exist in the swath of the lopsided risk-contracting methods.

Financial-risk contracting between HMOs and provider groups is an ongoing tug of war. From one perspective, financial risk that can be fully managed by the provider group should be fully transferred (capitated) to that provider group from the HMO. Ideally, financial risk that is less manageable by the provider group should be retained by the HMO in increments proportional to the manageability of the financial risk, including volume (units) and price per unit. In general, pharmacy providers have very little control over either price or volume and generally should not assume financial risk associated with a prescription drug benefit. The HMO (insurer) controls the drug benefit design, including scope of drug coverage, copayment amounts, and days supply per copayment, etc. The HMO (or health plan), not the pharmacy provider, controls the rebates obtainable from pharmaceutical manufacturers, and pharmacy providers have little opportunity to influence (reduce) price except for small discounts earned through volume purchasing or through therapeutic selection if the HMO administers a true low net-cost drug formulary.

Physician medical groups have some degree of control over volume and price in prescription drug benefits of HMOs and may, therefore, reasonably assume some degree of shared financial risk. Physicians can control price through therapeutic selection of generic drugs and lower-cost brand drugs. Physicians also have a considerable amount of control over the volume of prescription drugs provided to a given population of patients.

Drug benefit financial risk is measurable and even predictable for large HMOs, and historical experience, measured per member per month (PMPM) with defined populations of continuously enrolled members-patients, can help reduce the uncertainty of unknown future costs. However, physician medical groups are also dependent on HMOs to share reliable information to help predict future costs. In the 1990s, allegations were made that some HMOs were setting PMPM capitation rates, including drug benefit financial risk, as a percentage of premium, using unadjusted historical costs and growing enrollment through artificially low monthly premium rates. A Texas state court judge ruled in May 1998 that a given HMO must stop immediately its practice of penalizing physicians who exceeded their pharmacy risk-budgets, calling the policy “probably illegal.” An executive at the HMO acknowledged that the first drug benefit capitation rate was “too low” (at 9.6% of premium).

In October 1998, a large medical service organization (MSO) representing an independent practice association (IPA) of physicians in North Texas terminated its risk-contract with one of the largest HMOs in the country for not providing claims data in a timely and complete manner, making it impossible for the MSO to manage financial risk. Subsequent negotiations between the large HMO-insurer and the MSO resulted in some strong-arm tactics that attracted national attention and the intervention of the American Medical Association. The presidents of the Dallas County Medical Society and the Texas Medical Association (Austin) released a joint statement that included the following assertion: “Remember, this is an HMO that cannot, on a daily basis, tell its contracting doctors where or who its patients are, what kind of medications they are taking, or even what hospital they are in.” The dispute attracted the attention of the Texas Department of Insurance and the U.S. Justice Department, which penalized the insurer in a consent decree that required significant asset divestures in key Texas markets. In early 1999, an independent practice association in San Mateo, California, notified the same large national insurer that it would not renew its contract, in part because the IPA could not obtain accurate and timely medical claims data. The IPA claimed that “We could never seem to get information on admissions, bed-days, etc.”

Business practices that either leave provider groups with unmanageable medical or drug costs or fail to provide the risk-contracted providers with the claims data necessary to manage the financial risk may result in state restrictions on risk contract terms. The Texas Department of Insurance, for example, prohibited HMOs from transferring financial risk for prescription drugs to medical groups following the unfair capitation rates and financial-risk practices for prescription drug benefits risk that devastated several physician groups in North Texas in the late 1990s. HMOs in Texas may provide financial incentives to physician groups for managing prescription drug costs but are not permitted to transfer financial risk for prescription drug benefits to physicians.

In this issue of the Journal, Agnew, Stebbins, Hickman, and Lipton describe the results of a survey of physician groups surrounding the subject of the management of financial risk associated with the growing use of self-administered injectable (SAI) drugs. As the relative magnitude of cost of this category of medical costs grows, more attention will be paid to the methods to manage these SAI drug costs effectively. The present survey, sponsored by a grant from the Robert Wood Johnson Foundation, seemed to find that many physician groups under contract with HMOs had not, as of early 2001, adopted a sophisticated or thorough cost management strategy for SAI drugs. This finding is really not surprising because the utilization of SAI drugs has grown more dramatically since that time, particularly in the categories of SAI drugs for hepatitis C virus (e.g., interferon SAIIs with ribavirin), multiple sclerosis (e.g., beta interferons and glatiramer acetate) and rheumatoid arthritis (e.g., etanercept). What is surprising is that at the time
Evidence-based Medicine, Practice Guidelines, and Disease Management

Early in 2003, the Agency for Healthcare Research and Quality launched the Web-based National Quality Measures Clearinghouse to function as a repository for evidence-based quality measures and measure sets.\(^1\) In January 2003, Kaiser Permanente announced that it would make available on its Web site more than 100 clinical practice guidelines (CPGs) that are used by Kaiser doctors for treatment of Kaiser HMO members.\(^2\) CPGs are the operational (process) part of interventions to improve clinical, service and cost outcomes. CPGs are necessary to operationalize the evidence that results from the conduct of randomized controlled trials (RCTs). Without CPGs, it is possible to systematically applyRCT evidence to real-world clinical practice. When CPGs are defined clearly and in sufficient detail, it is possible to use feedback from performance measures to continually improve care in a disease management program.

Disease management programs are difficult to design, implement, operate, and maintain,\(^3\) and, even today, there remains considerable frustration over the inability to reliably measure the financial value of disease management programs.\(^4\) In this issue of the *Journal*, Cannon, Larsen, Towner, et al. describe a health systems-wide effort to improve clinical outcomes in diabetes.\(^5\) The authors report statistically significant and clinically important improvement in diabetes care according to 6 key performance measures: percentage of diabetics with at least 1 recorded hemoglobin A1c measurement per year, percentage of diabetics with hemoglobin A1c greater than 9.5, percentage of diabetics with hemoglobin A1c less than 7, percentage of diabetics with at least 1 recorded low-density lipoprotein (LDL) measurement per year, percentage of diabetics with recorded LDL value less than 130 mg/dL, and percentage of diabetics with at least 1 eye exam per year. The authors do not report an estimated return on investment in the diabetes care management system (DCMS) at this integrated health system.

The investment in care process models (CPMs) at Intermountain Health Care (IHC) is, in fact, large. Brent James, MD, and his colleagues at IHC have worked for nearly 20 years to create CPMs and measure their effects on clinical and service outcomes. James is fond of saying that clinical practice improvement will result in greater efficiency and, therefore, have a favorable effect on cost outcomes as well as clinical and service outcomes.

The results of the DCMS reported in this issue of the *Journal* are nothing short of exciting. Yet, readers should recognize that (a) this integrated health network (IHN) has been in the business of producing, implementing, and continually improving CPMs for nearly 20 years and (b) this is not just another integrated health system. SMG Marketing, now Verispan, has found IHC to be among the top integrated health systems in the United States since it began the measurement of integrated health systems 5 years ago. As of March 1999, this IHN ranked number 15 among all IHNs in the United States.\(^6\) SMG Marketing ranked IHC number one among 532 IHNs in 1999.\(^7\) In year 2000, Sentara Healthcare (Norfolk, VA) edged out IHC as the most integrated health network in the United States by these measures,\(^8\) but IHC reclaimed the top spot in 2001\(^9\) and held on to the top spot among 472 IHNs assessed in 2002.\(^10\) IHC had about 2,000 beds among 21 hospitals in 2002, in addition to the physician division and insurance division, including IHC Health Plans.

The Relative Value of Disease Management Programs Versus Drug Manufacturer Rebates

When the State of Florida in 2001 proposed a plan to extract additional rebates from prescription drug manufacturers through imposition of a preferred drug list (PDL) tied to a prior-authorization process, selected prescription drug manufacturers made counter proposals to sponsor disease management programs in lieu of paying additional rebates. In September 2001, Florida agreed to a proposal that projected savings of $16.3 million from establishment of 2 community-based disease management programs, one to hire health professionals and social workers to attend to Hispanic and Mexican-American Medicaid recipients with depression, HIV/AIDS, breast cancer, cervical cancer, or lung cancer. The explicit goal of this disease management program was to improve compliance with health regimens, including drug regimen adherence.\(^11\) The second disease
management program would hire and train community residents to help overcome language and cultural barriers to obtaining access to care for Medicaid recipients with depression and cardiovascular disease. The “savings” would apparently be measured in reduced emergency room visits and hospitalizations. The Pharmaceutical Research and Manufacturers of America (PhRMA) contested the Florida Medicaid program efforts to extract “supplemental” rebates, but a federal judge in the U.S. District Court in northern Florida (Tallahassee) ruled on December 28, 2001, that the Florida Medicaid list of preferred drugs may influence patient and physician behavior but did not prevent access to nonpreferred drugs, which would be illegal under federal law. In September 2002, the Eleventh Circuit Court of Appeals (Atlanta) upheld the lower court’s ruling regarding the Florida program, and the legality of Medicaid supplement rebate programs based upon PDLs with prior authorization was bolstered by the decision from Federal Court Judge John Bates in Washington, DC, on March 28, 2003, regarding a similar program in Michigan that employed a PDL with prior authorization.

The value of disease management programs in lieu of concessions in direct drug cost was disputed by a report from the Office of Program Policy Analysis & Government Accountability (OPPAGA) of the Florida legislature in early 2003. OPPAGA found that the disease management programs in Florida sponsored by prescription drug manufacturers saved the state about $35M in 2002, about $30M short of the amount that the drug companies would have paid in supplemental rebates. In 2001, Florida’s PDL saved the state $123M, including $46M (37.4%) from supplemental rebates. OPPAGA recommended to the Florida legislature that supplemental rebates be required for all drugs on the PDL and that the disease management programs be funded from a portion of the supplemental rebate income. OPPAGA analysts also said that the methodologies used by the drug companies to calculate savings from the disease management programs were vague, and some experts opined that the drug manufacturers had not been able to show that their disease management programs save money despite offering these programs to health insurers and others since the mid-1990s.

From another perspective, it is easy to see why the pharmaceutical manufacturers are opposed to the heavy-handed managed care method imposed by prior authorization (PA). The PA process in Florida produced dramatic market share changes that would be the envy of managed care pharmacists in the private sector. In just 90 days, the market share of lansoprazole increased by an absolute 21 percentage points, or 55% in relative terms, from 38% of prescriptions for proton-pump inhibitors in the second quarter of 2001 to 59% of prescriptions for proton-pump inhibitors in the third quarter of 2001. Lansoprazole market share increased further, to 67% of prescriptions in the fourth quarter of 2001. Stated another way, by paying supplemental rebates, the manufacturer of lansoprazole was able to nearly double its market share, a relative increase of 76%, or 29 absolute percentage points, in just 6 months, at the expense of competitor omeprazole, which experienced a market share drop of 33 percentage points, from 49% in the second quarter of 2001 and to 16% in just 90 days in the third quarter of 2001. The market share erosion for omeprazole was essentially 100%, to a residual of 1% of prescriptions for proton-pump inhibitors in the first quarter of 2002, a period of just 9 months.

Disease Management, Pay-for-Performance, and Clinical Pharmacist Interventions in Diabetes Care

The April 2003 issue of a business news magazine contained 2 articles on the same subject, but the editor did not make an apparent connection between the articles and their common subject. More surprising, both articles were written by the same author. Certainly, the titles of the articles were different and would not suggest a connection: “Pay-for-performance plans seek to cut costs,” and “Pharmacist oversight cuts cost of chronic disease.” One article touted the “unique” notion of paying physicians to attain certain measures of disease management, in an employer-sponsored program called “Bridges to Excellence.” The separate, front-page article, touted the value of pharmacists in managing chronic disease, particularly diabetes; incidentally, the pharmacists were compensated for the professional interventions. The former article reported that several large employers had invested in a scheme, labeled Bridges to Excellence, with the intended purpose of reducing future costs of chronic disease, specifically diabetes. The (physician) pay-for-performance program had the same expected outcomes as the pay-pharmacist program, the regular, routine use by patients of measures to better control serum glucose and thereby delay the onset and reduce the magnitude of complications of diabetes.

The pharmacist pay-for-outcomes program, the “Asheville Project,” involved payment of $38 per monthly visit to participating pharmacists who monitor medication adherence and the routine use of serum glucose measures and perform basic physical exams to detect foot care or other health problems that may warrant a medical visit to a physician. The City of Asheville, a primary sponsor of the pay-pharmacist disease-management program for diabetes, reported savings of $2,000 per diabetic patient per year, largely as a result of reduced hospital costs. Average total medical costs per diabetic patient were reported to be $7,082 prior to implementation of the pharmacist disease management program for diabetes, an average $5,210 (26% less) in the first year and $4,651 in year 2, a 34% reduction compared to base-year costs. The Asheville Project included incentives for patient participation, including the elimination of copayments for visits to pharmacists and diabetes drugs and supplies, and provided each participating patient with a glucose meter.

Consensus Panel, National Guidelines, and Other Potentially Misleading Terms

A recent article trumpeted in its title, “Consensus Panel Recommendations” for “Asthma Treatment Guidelines.” The
panel of 16 physicians and 2 pharmacists appeared to have the credentials necessary to adequately address the subject. However, the work of the panel and the article that was derived from this work were funded by the manufacturer of the drug that the panel recommended for use in patients with moderate to severe asthma that is “suboptimally controlled.” This observation gives the reader pause. Should not national treatment guidelines be based upon evidence from randomized clinical trials and developed by independent experts who do not benefit from or have a direct commercial interest in the recommendations that evolve from such panels?

What is the necessary amount of independence for these experts? Some may argue that experts employed by health plans are biased toward treatments and care processes that are concerned about cost. On the other hand, physicians and other providers engaged in clinical practice generally want what is best for their patients and may have little interest in cost, particularly for insured patients. Disclosure of potential conflicts of interest and sources of funding is a fundamental tool to manage bias, but most would agree that consensus panel guidelines should not be developed by persons compensated by the company that stands to benefit from the use of these guidelines. For busy readers, perhaps such treatment guidelines should include titles such as “Consensus Panel Recommendations Sponsored by XYZ Company.”

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