I. Integration of Pharmacy and Medical Benefits and the Prominence of Pharmacy Benefits Management

Healthcare reform is evoking change in pharmacy benefit management. Pharmacy and medical care must become more integrated to create affordable drug programs to align with accountable care organizations (ACOs) and health insurance exchanges (HIExs) lines of business perpetuated by the Affordable Care Act (ACA) and increasing regulation of healthcare delivery. Managed care techniques such as narrow pharmacy networks, integrated care programs, medication therapy management, cost trend management of specialty pharmacy drugs, and pay-for-performance models resulting from implementation of the ACA will help mitigate the potential adverse impacts of healthcare reform on the pharmacy component of healthcare, as well as highlight pharmacy benefits as a prominent feature in post-ACA healthcare delivery. Such adverse impacts include the potential for employers to discontinue sponsored plans for employee groups as the Shared Employer Responsibility Penalties under the ACA are likely to be lower than spiraling health plan costs. A decrease in employer-sponsored plans may itself trigger both increased healthcare costs as well as adverse selection in group and individual HIExs as employees flock to them for coverage.

Successful ACO models contemplate greater integration of data, incentives, care plans, and healthcare services. Integration of medical and pharmacy data will become essential to a successful ACO. With greater accountability for patient outcomes, providers will increasingly rely on pharmacists for patient-specific medication information, identifying and managing gaps in care, and providing medication reconciliation at care transition points.

The growing impact of Medical Loss Ratio (MLR) requirements, ACOs, and HIExs under the ACA should produce economic benefits for all players in the managed care marketplace and will also enhance the role of pharmacy in managed care. Continued pressure to reduce unnecessary administrative costs that could adversely affect MLR requirements could elevate the role of pharmacy once healthcare reform is fully implemented. More costs of drug utilization management programs could be attributed to MLR if the quality management aspects of such programs had stronger measurement and reporting to support their clinical value.

Much of the current regulatory guidance on ACA implementation does not address pharmacy issues for ACOs or HIExs in much detail. Greater guidance from regulatory authorities will be necessary. Furthermore, separation of risk among payers and providers within government-prescribed ACO models may not effectively incentivize efficiency and cost containment. Pharmacy risk resides with payers, while medical risk is shared with, or shifted to, providers. This will have to be addressed as reform efforts progress in order to achieve optimal cost containment. The belief is that commercial ACO models will follow the same approach for now. Eventually, however, the private models must move toward integrating pharmacy and medical expense in terms of financial risk to maximize efficiency. Some plan sponsors (integrated health systems and managed care organizations) are already successfully integrating these benefits/risks. However, other organizations where pharmacy and medical have historically been treated separately may continue to resist integration until it becomes a recognized market trend and its economic savings are fully realized.
Aggressive management of the drug benefit and of the pharmacy network is critical to the ability of the MCOs to provide affordable access to drugs, which are a growing cost component in healthcare. Value-added programs such as medication adherence programs should result in overall cost reduction. However, this too depends upon integrating pharmacy and medical claims and the systems relied upon to capture data to support such cost reduction. These integrated systems are prerequisites to new types of contracts that will include medical outcome guarantees and mechanisms to attribute value to different stakeholders for specific activities and/or outcomes.

II. PBM Compensation Disclosure

Federal regulators have historically concluded that “vigorous competition in the marketplace for pharmacy benefit managers (PBMs) is more likely to arrive at an optimal level of transparency than regulation.” Indeed, many commentators have asserted that state-level regulation of the PBM industry is unnecessary and that misguided administrative actions by regulators that do not fully understand the complexity of the PBM will not facilitate transparency or cost containment. However, the federal government also recently enacted mandatory disclosure regulations. Statutes enacted as part of the ACA require PBMs to disclose competitively sensitive information to certain health plan sponsor clients and to the federal government. Specifically, the ACA requires PBMs that manage drug coverage under a contract with a Medicare Part D drug plan or qualified health benefits plans offered through a state exchange to disclose certain financial and prescription drug dispensing information relating to their client contracts. The required information includes: (1) “the aggregate amount, and the type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan,” (2) “the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor,” (3) the total number of prescriptions that were dispensed,” and (4) “[t]he aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies . . . .” From this information, PBMs can calculate amounts relevant to the contractual arrangement between the PBM and health plans or insurers. PBMs save healthcare payors as well as insureds and plan members billions of dollars annually by controlling drug cost, incentivizing insureds and members as well as providers to lower cost generic alternatives and monitoring utilization. Mandatory disclosure requirements, however, do not address disclosure of these savings.

The federal laws under the ACA include provisions to protect the confidentiality of information disclosed by the PBMs. However, as with response to state regulations which have been promulgated in several states, it is unclear whether these provisions will be sufficient to prevent the competitively sensitive information from leaking to other participants in the prescription drug market. The District of Columbia, Maryland, South Dakota, and Vermont all require PBMs to disclose information concerning agreements and rebate arrangements between PBMs and prescription drug manufacturers. Similarly, North Dakota allows health plan sponsors to directly audit PBMs’ accounts and records to confirm that the PBMs are sharing the rebates they receive from manufacturers with the sponsors according to their contracts. Most of the state regulations include provisions allowing PBMs to classify information disclosed to health plan sponsors as confidential. The District of Columbia is one example. Without a court order or consent of the PBM, a PBM in the District of Columbia providing information to a covered entity designated as confidential has a valid expectation that the information so designated will not be disclosed to third parties. Indeed, in many jurisdictions, information designated as confidential may not be disclosed by the covered entity to any other person or entity without the consent of the PBM. However, these confidentiality provisions are often vague and inadequate.

In 2012, the U.S. Department of Labor (Department) issued regulations requiring providers to disclose direct and indirect compensation to pension plans (Section 408(b)(2) Regulations). The Department reserved the question of whether the Section 408(b)(2) Regulations should apply to welfare benefit plans. In 2014, the Advisory Council on Employee Welfare and Pension Benefit Plans (the Council) examined whether PBMs should be required to disclose fees and compensation to sponsors of ERISA health plans in order for sponsors
to satisfy their obligation to pay only reasonable compensation to entities that provide goods and services to ERISA plans. After receiving testimony and information from multiple sources, including representatives of PBMs, plan sponsors, plan consultants, plan auditors, pharmacy groups, governmental agencies, and other interested persons, the Council recommended that the Department should consider making Section 408(b)(2) Regulations applicable to welfare plan arrangements thereby deeming such arrangements “reasonable” only where PBMs disclose direct and indirect compensation, including compensation paid among related parties (such as subcontractors), in a manner consistent with current Section 408(b)(2) Regulations. The Council further recommended that the Department consider issuing guidance to assist plan sponsors in determining whether and how to conduct a PBM audit of direct and indirect compensation.

As the ACA is fully implemented and the ACO models mature, integration of pharmacy and medical components of healthcare will continue. Transparency among all stakeholders including PBMs, will be critical under the ACA. The role of pharmacy will continue to rise in importance to achieve efficiencies and economies of scale in healthcare delivery.

Endnotes

2. Id.
7. See 42 U.S.C. § 1320b-23(c) (Supp. V 2011) (“Information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary or by a plan receiving the information . . . .”)
8. See D.C. Code § 48-832.01(c)(1)(B) (2012); Md. Code Ann., Ins. § 15-1624(a) (LexisNexis 2012); S.D. Codified Laws § 58-29E-4 (2004); and 18 V.S.A. § 9472(c) (2012) (all of which mandate different degrees of disclosure under various circumstances).
11. 29 C.F.R. § 2550.408b-2.