

FEASIBILITY AND IMPACT OF INCLUDING ANTIPSYCHOTIC PRESCRIPTIONS INTO THE ACTUARIALLY SOUND CAPITATION RATES FOR THE PIHPs

(FY2010 Appropriation Bill - Public Act 131 of 2009)

April 1, 2010

Section 288: By April 1 of the current fiscal year, the department shall report to the house and senate appropriations subcommittees on community health, the house and senate fiscal agencies, and the state budget director on the feasibility and impact of including antipsychotic prescriptions, net of actual rebates, into the actuarially sound capitation rates for the PIHPs. If this initiative is feasible, the report shall include a proposed implementation plan.

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MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
BOILERPLATE REPORT
SECTION 288

Consideration: Who prescribes the atypical antipsychotics?

One argument favoring capitation of antipsychotic medications to the PIHPs posits that doing so would more closely align financial responsibility with clinical practice, thus optimally balancing the costs and benefits of prescribing decisions. The argument entails an assumption that PIHPs prescribe the vast majority of atypical antipsychotics. It turns out that this is not true; a maximum of 63% of pharmacy claims for antipsychotics are associated with PIHP consumers or PIHP-physician prescribing.

PIHPs would be placed in the position of financial responsibility for this pharmacy benefit without any authority or practical ability to manage the costs associated with non-PIHP prescribing. PIHPs would be administering a pharmacy benefit for individuals for whom they do not provide services. Aside from the practicality, CMS is unlikely to approve such an arrangement.

Because the required format for pharmacy claims is not designed in such a way as to discriminate prescriptions written at PIHPs from those whose written by fee-for-service (FFS) or health plan providers, it is not possible to identify either at the pharmacy point of sale or through state warehouse data those paid pharmacy claims written by a PIHP prescribing physician.

At best, a comparison can be made of individuals for whom Medicaid pharmacy claims for antipsychotics were paid with individuals receiving PIHP services. An FY2008 comparison of consumers receiving an antipsychotic medication and PIHP encounter data identified that no more than 63% of claims for this class of medications were for individuals that also received any kind of service from the PIHP at any time during the year that the prescription was filled. It is highly likely that fewer than 63% of these prescriptions come from PIHPs, as a consumer may undergo evaluation or brief treatment at a PIHP while continuously receiving medications from a health plan or FFS practitioner. Note that FY 09 service data was not available in time for this comparison to be made more currently than FY 08.

Thus, a minimum of at least 37% of claims for atypical antipsychotics reflect prescriptions for patients who are not PIHP clients. This suggests that a significant fraction of these drugs are used for conditions that fall short of the threshold of serious and persistently mentally ill that ordinarily triggers enrollment in a PIHP or for individuals whose recovery may not require PIHP services while medications remain necessary. Both new Food and Drug Administration (FDA)-approved indications for atypical antipsychotics and off-label (not FDA approved) uses have expanded dramatically in the last decade. Alternative indications likely account for a significant fraction of these prescriptions. Patients without serious mental illness may have nonetheless benefited substantially from their availability.

It is fair to conclude that capitation of the atypical antipsychotic benefit to the PIHPs for the 37% or more of prescriptions written elsewhere would only make sense if the PIHPs can have knowledge of and/or control prescribing irrespective of the consumer's relationship to a PIHP. Whereas PIHPs can exert some influence on employees and contractors through education, academic detailing, or utilization review techniques, none of these strategies are likely to influence FFS and HMO prescribers from multiple disciplines, including family practice, pediatrics, neurology, internal medicine, geriatric medicine, and psychiatry, who do not answer to the PIHPs, since those physicians have no relationship to the PIHPs.

Conversely, PIHPs would be reluctant to assume responsibility for decisions about medications prescribed for Medicaid recipients who are not their clients and whose principle problems may not be psychiatric in nature. Without PIHP authority to guide all antipsychotic prescribing, capitation to the PIHPs transfers financial risk and responsibility without a means to manage utilization, quality or access. Furthermore, the PIHP would become accountable for managed care administrative functions including quality of care, grievances and appeals while there is no practical authority for non-PIHP consumers,

Regulatory Consideration: CMS

Changes in the terms of Michigan's Medicaid waivers require approval from CMS. The uniqueness of the proposed capitation of antipsychotic medications for all Medicaid beneficiaries into the PIHP plans would trigger a longer review to address, among other things, the actuarial soundness of the plan, meaning the rates are reasonably sufficient to meet the costs, access and quality of care, and the capability of the PIHP to effectively carry out its responsibilities.

Balanced Budget Act of 1997 requirements apply; therefore rates must meet the standard of actuarial soundness. The availability of rebates is essential to establishing capitation rates at current costs. The rate must be inclusive of rebate revenue since the pharmacy must be paid the cost before rebate. Data on rebates for specific antipsychotic medications is not available, but the average rebate for brand name drugs on the Michigan formulary is in excess of 40% for those drugs to which rebates apply. Inclusion in the PIHP rates of the cost of these medications net of the rebate would not meet actuarial soundness requirements.

The capacity of the PIHPs to bear the risk of drug capitation is an important consideration. The challenges involved are unfamiliar territory for most PIHP administrators who will have relatively little margin for error in stewarding the distribution of large volumes of expensive drugs. The only Medicaid financial risk management tools available to a PIHP are the internal services fund (ISF) and the risk-sharing agreement with the state that caps liability at 7.5% in excess of the capitation at which point the state is at risk. Utilization of ISF or other savings for these purposes simply erodes the service benefit.

Capitation would supply the PIHPs with a powerful incentive to contain costs. Under an open access model, in which prescribers are free to prescribe without conventional formulary constraints such as prior authorization, step edits, etc., the PIHPs would be forced to rely mainly

on cost reduction efforts related to education and utilization review. To some extent these already exist at the state level with minimal evidence of savings.

PA 248 and the “Open Access Principle”

A key factor in this discussion is PA 248 of 2004. This statute, giving force of law to the “open access principle,” prevents the Michigan Pharmacy and Therapeutics Committee from placing prior authorization restrictions on antipsychotic drugs. It does not impose similar constraints upon health plans, though MDCH contractually requires the Medicaid Health Plans to conform to the provisions of PA 248. The statute does not affect the PIHPs, which have never borne responsibility for Medicaid pharmaceutical benefits, but there would be an expectation that these consumer protections are extended to a capitated PIHP pharmacy benefit, whether by statute, contract, or dictate. Public policy can change, of course, and clarity on the legislature’s intention with respect to use of aggressive formulary controls such as prior authorization is critical in assessing the viability and impact of any capitation scheme.

As a conceptual and practical matter, the open access principle undermines the very techniques that make managed pharmacy benefits desirable. In short, capitation and open access are inconsistent approaches to pharmacy.

PIHP Administrative Burden

Introduction to the PIHPs of a large pharmacy benefit will require new hiring, a steep learning curve, and an immersion in psychopharmacology that will be challenging, unfamiliar, and perhaps unwelcome. It is estimated twelve months would be required for all PIHPs to develop these capacities after CMS approval had been obtained for the changes.

Implementing capitation would require pharmacy expertise within the staff of the PIHP to represent the organization’s interests in negotiations. Formulary development would create new roles for medical directors and other psychiatrists, and intelligent management decisions would require the capacity to analyze and conceptualize claims data. These and other functions would add to the net administrative burden of the pharmacy Medicaid benefit but would not per se prevent successful implementation.

A few PIHPs have developed special relationships with pharmacies, but most have no prior experience in managing a formulary or a drug benefit and their employees lack expertise, indeed even familiarity with the relevant tasks. Full-time psychiatrists as employees are the exception rather than the rule, physicians having a limited role in administrative functions in many community mental health systems. The smaller and more remote community mental health settings have part-time psychiatrists.

On the other hand, much of the technical expertise required to carry out a capitation program is available from pharmacy benefit managers who routinely contract with managed care plans to handle most major tasks such as negotiating rebates, creating provider networks, paying claims,

and creating the information technology infrastructure needed for billing and pharmacy management.

The PIHPs likely would find it in their best interests to collaborate for purposes of managing such a benefit, thereby to maximize the efficiencies and bargaining advantages of a larger group. Similarly, adopting a single formulary scheme would be easier and less expensive than adopting eighteen different formularies (though under open access, all formularies would be the same.)

If PIHPs choose to form a formal collaboration to hire a single PBM, legal authority must be available. According to the Michigan Association of Community Mental Health Boards, “CMHAs and CMHSPs are limited in their ability to individually or collectively establish new business structures. It is possible, however to use the ITFRA [intergovernmental transfers of functions and responsibilities act, MCL 124.531 et seq] and/or UCA [Urban Cooperation Act, MCL 124.501 et seq.] statutes to develop vehicle(s) which could be applicable to such an endeavor. Assuming the vehicle is legally sound and adequately resourced, it most certainly creates additional administrative burden and layer(s) to Medicaid benefits management for the PIHPs.” (MACMHB, 2010) Differences of opinion concerning formulary structure and practices, cost-control measures such as prior authorization and quality review, and representation on formulary and utilization committees, could impede development of the coalition.

Administrative Requirements

PIHPs would encounter new administrative expenses in overseeing the antipsychotic benefit for development of local expertise in pharmacy and retention of an external PBM. The state’s administration costs may diminish slightly, the total remaining volume of prescriptions dropping to some extent, but the advantage would be trivial, since the fundamental structural costs of administering the FFS program would not change. Some revenue would return to the PIHPs through application of the use tax (Public Act 440 of 2008).

Implementation

Implementation of a capitation scheme would require the following:

- approval of the plan by CMS
- resolution of regulatory and oversight issues arising from the Balanced Budget Act and the Health Insurance Portability and Privacy Act;
- development of state policy including parameters of capitation,
- oversight procedures;
- decisions about PIHP authority over prescribing by non-PIHP clients and
- management of disputes between health plans and PIHPs;
- education of PIHPs about business and clinical implications of capitation;
- possibly, development of a business entity comprising most PIHPs; approval of such a business entity by participating county authorities; hiring of internal experts by individual PIHPs and of administrative staff for the coalition;retention of one or more pharmacy benefit managers (PBM),

- key decisions about handling of claims and payments from multiple PIHP catchment groups;
- key decisions, probably at the PIHP level, regarding the number of formularies, creation, authority, and composition of formulary committees;
- writing policies and procedures by PIHPs, including mechanisms for review of denied requests and claim disputes;
- PBM development of the pharmacy benefit plan, pharmacy network enrollment, data exchange capability with PIHPs; adaptation of pharmacy software to new formulary processes, including customer identification; and education of providers (including PIHP, FFS, and MHP providers)
- Data transfer agreements; the PBM(s) would require daily eligibility files for both PIHP and non-PIHP consumers (e.g. the entire Medicaid eligibility file)

Clinical Impact

Carving in these medications creates two distinct pathways for access to antipsychotics, on the one hand, and for all other drugs, on the other. Even if consumers are largely unaware of the systematic changes, they will quickly become aware of any system failures. Beneficiaries would be required to obtain medications through two separate benefits.

The clinical impact depends upon cost-control mechanisms likely to be employed, which in turn depend upon the extent to which an open access principle governs formulary management. Under an open access model capitation should not have important clinical effects related to formulary content and prescribing patterns. There is significant danger, however, that in overhauling a large system access will be interrupted for some Medicaid recipients because of inevitable errors in implementing complicated new processes.

Absent an open access mandate, PIHPs would be required to manage these drugs much as HMOs manage branded medications. There may be differences in how individual PIHPs approach the task that create discontinuities in delivery of care across the state, though a narrowing of open access could promote more homogeneous prescribing patterns.

Dramatic changes in drug access and complicated rules for obtaining specific pharmaceuticals are undesirable. Studies have demonstrated that interruptions in treatment result from such changes and, when interruptions occur, overall costs of providing care usually rise. Although most beneficiaries outside of Medicaid, including dual eligibles who are subject to one of many Medicare part D formularies, enjoy something less than complete access to all psychotropic medications, there is no evidence that harm inevitably results from differences in formulary content. Rapid changes in access, administrative errors, and overly restrictive formularies, however, do produce poor outcomes. Thus, the impact of a capitation plan that abandons the open access principle depends upon the menu of restrictions imposed at the PIHP level.

Some formulary policies, such as a prior authorization requirement that limits simultaneous prescription of multiple antipsychotics, may benefit patients, while others that promote use of first generation antipsychotics could result in higher rates of hospitalization and side-effects such

as tardive dyskinesia. Capitation as such does not guarantee either a favorable or an unfavorable outcome from a clinical perspective. It is not consistent, however, with an open access policy.

Comparison with Other States

Today, Michigan falls squarely in the mainstream with respect to its approach to behavioral pharmacy. According to a recent survey of 31 state mental health medical directors belonging to the National Association of State Mental Health Program Directors (NASMHPD) Michigan was among 20 states that offered “open access” to most psychotropic medications, including antipsychotics, while several of these states were considering new restrictions. Eleven states imposed restrictions through preferred drug lists or similar mechanisms.

Arizona is apparently the only state that capitates psychotropic medications to its PIHPs (known there as RBHAs or “Regional Behavioral Health Authorities”). Mental health populations are divided between the Arizona Health Care Cost Containment System (AHCCCS), which provides general health care to Arizona Medicaid recipients under a managed care model, and the RBHAs, which supply care on a capitated basis to the more severely ill. AHCCCS primary care providers treat uncomplicated depression, anxiety and ADHD, while the RBHAs treat seriously mentally ill and child/adolescent consumers. A limited mental health formulary is available to primary care practitioners from AHCCCS, which pays for psychiatric drugs prescribed in its network.

For the RBHAs, the state specifies minimum contents of psychotropic formularies, but the RBHAs are permitted to modify this with conditions such as prior authorization, contingent upon state approval. Atypical antipsychotics are almost exclusively prescribed by the mental health authorities and rarely, if ever, by the health plans.

Arizona clinical protocols guide prescribing, while pharmacies appear to have a role in monitoring and enforcing protocols. Prior authorization is required for prescription of multiple atypical antipsychotics (polypharmacy) and for using doses exceeding FDA recommendations.

Summary

As described in this report, incorporating antipsychotic medications into the PIHP benefit is not considered feasible. There is no evidence that excessive costs are generated by the PIHPs or that large savings could be achieved even with aggressive management. The absence of a large menu of generic alternatives to first-line branded drugs limits one of the most important prerogatives of managed pharmacy, the capacity to promote generic prescribing which, in some HMO’s, achieves rates as high as 70-80% for non-psychiatric drugs. More likely targets for savings lie in atypical use for persons without severe mental illness. This is not to say that prescriptions for these consumers are necessarily inappropriate medically, only that less expensive options may be available for non-psychotic disorders that would not be good substitutes in treating schizophrenia and other severe illnesses.

As outlined earlier in this report, at a minimum, 37% of these medications are prescribed outside the PIHP system; there is strong likelihood that CMS would not find this model adequately

assures access or quality of care and actuarial soundness net of rebates is questionable. Only one state has implemented such a model, but with limitations in access.

Capitation would occur at the cost of diverting the administrative focus of the PIHPs from existing missions and by incurring new risks related to the novelty of the plan and the inexperience of the PIHPs in pharmacy benefit management. If administrative adjustments to PIHP capitation were accomplished flawlessly, the clinical impact of these changes would be minimal; discontinuities in treatment are likely to occur during the transition period and may occur more frequently afterwards, owing to greater complexity in the system overall.

Finally, current Department of Community Health Mental Health/Substance Abuse administration resources are not sufficient to provide oversight.