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and Family Services  
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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA appreciates the opportunity to provide comments on key issues related to the Illinois Department of Healthcare and Family Services move to provide Medicaid patients with appropriate coordinated care.

### **1) How comprehensive must coordinated care be?**

Patients, particularly Medicaid patients with chronic disease, should have access to a team-based, coordinated care approach where a healthcare provider's goal is that the patient remains at the center of the health care delivery model. Today, one assigned healthcare provider actively monitors, educates, provides reminders, and follows a patient's progress over time. Studies have shown that coordinated care, along with the appropriate treatment with the right medicine, can reduce the costs of treating chronic disease and improve patient outcomes. Patients should have timely, unrestricted access to medicines that their healthcare providers feel can improve their health and, in the long term, limit complications that could result in costly, painful interventions such as outpatient procedures, hospitalizations, surgeries, and increased outpatient physician visits. Newly approved medicines and breakthrough therapies may offer the difference that a patient has been waiting for to be able to resume work or improve his or her quality of life in a way that was not achieved with other therapies.

There are multiple examples of patients whose lives have changed as a result of new breakthrough medicines in the area of mental health, pain, epilepsy, and in other chronic disease areas. Improved access and patient adherence to prescribed medicines not only lowers costs on other health care services, it also increases worker productivity. Healthcare providers should be allowed to exercise their clinical judgment as to what is best for their patient given the patient's pre-existing conditions, health history, pattern of compliance, and other relevant issues. Healthcare providers must have an arsenal of medications available to treat their patients most effectively.

In addition, coordinated care will promote quality of care, and improved health outcomes, by encouraging medication compliance (taking medications exactly as prescribed by the physician). Compliance failures may stem from barriers to coverage for the prescribed medicine. For example, increasing copayments can lead people to stop taking, or to skimp on, needed medicines.<sup>1</sup>

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<sup>1</sup> See, e.g., Tamblyn R, *et al.*; Adverse events associated with prescription drug cost sharing among poor and elderly persons. *JAMA*. 2001; 285:421-429; Goldman DP, *et al.*; Prescription drug cost sharing; associations with medication and medical utilization and spending and health. *JAMA*. 2007; 298:61-69; Wagner, TH, *et al.*; Prescription drug co-payments and cost-related medication underuse, *Health Economics Policy and Law*. 2008; 3:51-67.

Coordinated care can also protect patients from ill-advised medication switches. The designated healthcare provider can protect patients who have begun taking a prescription medicine by ensuring that any change in medications is prompted by medical considerations, rather than new coverage restrictions. This is important because of evidence suggesting that physicians or other healthcare providers may feel pressured to switch prescriptions based on insurance considerations. Therefore, patient centered coordinated care would ideally encompass all of these factors, ranging from diligent oversight of needed preventative tests, following strict care plans, patient education regarding treatment, and medication reconciliation among others.

One of the benefits of a coordinated care program is that it can be tailored to meet the needs of the patients it treats understanding that each coordinated care model may serve a different patient population, ranging in differences from disease state to geographic region. Thus, it is important that the state not negotiate anything that could hinder access to appropriate care for the patients who rely on care from their coordinated care program. Contemplation of controls such as a master pharmaceutical contract that would be available to all coordinated care entities assumes that all patients are the same and should be treated in the same way. This is not the case, particularly in the Medicaid population where patients may suffer from multiple diseases and need care that targets their unique needs. Medical care is not one size fits all - particularly as we move toward personalized medicine.

## **2) What should appropriate measures be for healthcare outcomes and evidence-based practices?**

The Illinois Department should consider standards that allow coordinated care programs to meet evidence based requirements in ways other than through evidence-based guidelines. While clinically sound evidence-based guidelines are very valuable in ensuring patients receive recommended care, additional policies may also be valuable in supporting evidence-based care (for example, via clinical decision support or shared decision-making tools that allow for incorporation of new evidence before the guidelines are updated).

Wherever possible, guidelines or other decision-support tools used by coordinated care models should rely on the work of relevant medical specialty societies. Illinois should also require that any evidence based requirements developed by coordinated care programs reflect input and participation from physicians in the relevant specialty areas. These programs should be required to update any evidence based medicine guidelines in a timely manner if new treatments become available, such as within three to six months. This is similar to the requirements for P&T committees under Medicare Part D to review new drugs. Additionally, the State should identify other specific opportunities for aligning coordinated care program policies on evidence-based medicine and patient-centeredness (for example, via patient involvement in coordinated care governance).

Quality measures are an important safeguard to ensuring provision of high quality care to patients. We believe that Illinois should rely on measures that represent consensus agreement on how to best treat a given condition, reflect all treatment modalities of the current standard of care, and can improve overall outcomes such as reducing hospitalization. Such National Quality Forum (NQF) endorsed measures have undergone testing, validation, and scrutiny to ensure that they provide accurate, reliable, and meaningful results.

It is also important to ensure that measures remain up-to-date with innovations in treatment so that patients have access to all appropriate therapies. We recommend that the state ensure that the initial

set of proposed measures reflect current best evidence for treatment of a given condition, including all treatment options of the current standard of care, so that patients receive quality care and such care is supported, not discouraged, by the care coordination program.

Further, PhRMA supports the inclusion of measures that evaluate outcomes whenever possible, as these types of measures must evaluate care across both an episode of care and the care continuum. As such, these types of measures are ideally suited to evaluate care provided by care coordination programs.

**3) To what extent should electronic capabilities be required?**

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**4) What are the risk-based payment arrangements that should be included in care coordination?**

Concerns with incentives in shared savings programs, such as those in coordinated care models, that could limit care are not new and have previously been raised by the Centers for Medicaid and Medicare Services (CMS) and the Office of the Inspector General of the Department of Health and Human Services (OIG). Both CMS and OIG have expressed concern that these types of arrangements could lead to: (1) “stinting on patient care”; (2) treating only healthier patients (“cherry picking”) and avoiding sicker (and more costly) patients and steering patients to hospitals that did not offer such arrangements; (3) paying physicians for patient referrals; and (4) unfair competition (“a race to the bottom” among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals).<sup>2</sup>

Both CMS and the OIG have considered safeguards for certain incentive payment and shared savings programs in order to address these concerns. While the safeguards are not all directly applicable to coordinated care programs, a number are instructive in this instance and we recommend that Illinois consider and build on the relevant guidance. We recognize that in the coordinated care context a significant portion of care will be subject to quality measures. We ask that the state consider those areas where financial incentives are present, but quality measures are not, as well as on the period when quality measures are reported, but not used in calculating shared savings.

For example, in 2008, CMS proposed an exception to the Stark law in the Medicare physician fee schedule proposed rule for “incentive payment and shared savings programs.”<sup>3</sup> While the exception was never finalized, some of the proposed conditions for the exception offer important safeguards that were intended to protect “the Medicare program and beneficiaries from [potential] abuses” described above. For example, one essential safeguard that was highlighted by CMS (and by the OIG in advisory opinions) was the assurance that physicians could still use the same items and

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<sup>2</sup> See, e.g., OIG Adv. Op. No. 09-06 (June 30, 2009)(proposed arrangement where a hospital agreed to pay a group of cardiologists a share of the savings attributable to specific changes in that group’s cardiac catheterization procedures); OIG Adv. Op. No. 08-16 (October 14, 2008)(proposed arrangement where a hospital agreed to pay a group of physicians bonus compensation based on meeting certain performance standards); OIG Advisory Opinion No. 08-15 (October 14, 2008) (proposed arrangement where a hospital agreed to pay a group of cardiologists a share of the savings attributable to that group’s cardiac catheterization procedures); OIG Adv. Op. No. 08-09 (August 7, 2008) (proposed arrangement where a hospital agreed to pay a group of surgeons a share of the savings attributable to cost-reduction measures implemented during certain surgical procedures); Medicare Physician Fee Schedule for 2009 Proposed Rule, 73 Fed. Reg. 38502, 38550 (July 7, 2008).

<sup>3</sup> 73 Fed Reg. 38502, 38548- 38558 (July 7, 2008).

services available prior to the arrangement and would continue to make patient-by-patient determinations as to the proper course of treatment.

Similarly, the OIG has issued a number of advisory opinions regarding requests concerning proposed arrangements where a hospital would share with a physician group a percentage of the hospital's cost savings arising from the physicians' implementation of a number of cost reduction measures recommended by the hospital.<sup>4</sup> The OIG detailed the key safeguards included in the proposed arrangements that were sufficient to warrant a decision not to seek sanctions against those arrangements. In addition to some of the safeguards included in the CMS proposed exception (noted above), the OIG highlighted that the proposed arrangements protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the physician groups. Likewise, the OIG highlighted in the advisory opinions that features such as distribution of savings within groups on a per capita basis can mitigate "any incentive for an individual physician to generate disproportionate cost savings." These types of criteria previously noted by both the OIG and CMS are examples of "best practices" for safeguards to promote access to care and avoid the stinting on care that a shared savings program could encourage in the absence of relevant quality measures.

**5) What structural characteristics should be required for new models of coordinated care?**

Any shared savings programs such as the coordinated care entities anticipated to play a role in the Medicaid reform law in Illinois should include a major role for both primary care providers and specialists. Both play a paramount role as far as clinical guidelines and processes in the coordination of care. Primary care providers are the foundation for most patient care. However, specialists play an important role in patient care generally but also are a key component in the coordination of care. For many patients, particularly those who suffer from certain conditions, specialists are the principle care providers. For example, cardiologists, endocrinologists, and oncologists are often the primary medical providers for those patients who suffer from heart conditions, cancer, or diabetes. The elderly also often rely on specialists as their first line of care. CMS stated that "coordination of care involves strategies to promote, improve, and assess integration and consistency of care across primary care physicians, specialist, and acute and post-acute providers and suppliers."<sup>5</sup> CMS went on to state that primary care physicians can "reduce unnecessary repetition of laboratory testing or imaging" by coordinating care with specialists.<sup>6</sup> Including that primary care providers as well as specialists ensures that the full continuum of care and expertise is available to all patients.

**6) What should be the requirements for client assignment?**

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**7) How should consumer rights and continuity of care be protected?**

Continuity of care is an essential piece of any coordinated care model. It is essential that the healthcare provider who is coordinating care for the patient have the autonomy and authority to

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<sup>4</sup> OIG Advisory Opinion. 01-1; Adv. Op. 05-5; Adv. Op. 09-06.

<sup>5</sup> 76 Fed. Reg. 19547 (April 7, 2011).

<sup>6</sup> *Id.* At 19537.

make treatment decisions that they feel is best, based on the patient's history and personalized care plan. In some organizations, treatment may be restricted, due to cost reasons. For example, healthcare providers prescribe brand name medications for their patients for a variety of reasons. Often, there may be fewer side effects associated with brand name medicines or the dosing regimen is easier for the patient (i.e., once a day versus three times a day), thereby encouraging patient adherence. Some plans try to switch patients to cheaper alternatives that may not be the best treatment for that patient. Regardless, healthcare providers should be the ones who choose the treatment regimen for their patients, taking into consideration their individual medical needs and pre-existing conditions.

The shift to coordinated care follows, in many ways, what states hoped would happen when they moved Medicaid patients from Fee-for-Service to managed care. Unfortunately, as this shift has taken place over time, the protections provided to Medicaid beneficiaries under OBRA 90 have slowly been chipped away. Thus, there has been a growing concern that more of those protections will be lost as additional Medicaid patients move into managed care and an even larger concern as they move into coordinated care programs.

Ideally, important patient protections will follow this vulnerable population as their health care systems are rerouted into cost conscious programs. Continuity of care and adherence are essential components for both wellness and cost savings. For this reason, ensuring that patients have access to the both the medical care and prescription medications that treat and manage their chronic conditions is important. Also, comprehensive coverage of prescription medication is vital to care and thus access to prescription medicines in any coordinated care program should be as good as, if not better, than that provided under fee for service. In the cost of overall health care, prescription drugs are cents on the dollar compared to more significant medical treatment such as emergency hospital care or long term care. Patients should also have access to transparent information about their rights both to care and in the event of a denial or restriction placed on their treatment. Importantly, they should be able to choose the coordinated care program that best meets their needs and not be pigeonholed into a program that best fits the cost savings needs of the coordinated care program or the state.

Additionally, the state should not mandate that insurers offer plans in both Medicaid and the Exchange as a condition of participation in either. Limiting plan access to either market will limit competition and run contrary to the intent of the Exchange, which is to broaden insurance market options for the uninsured. A state Exchange should facilitate the availability of health insurance plans that meet federal certification requirements of health plans as qualified health plans and not otherwise seek to exclude plans or limit consumer choices within these new marketplaces. While it will be necessary to organize the Exchange in such a way that facilitates an ease of movement between Medicaid and the Exchange, mandating participation in both as a requirement for participation in either will serve only to limit plans offered.

Finally, coordinated care entities should be required to prepare reports assessing beneficiary access to care, including new items and services. The report should detail the impact that the coordination care model has had on patient access to care, any new barriers to use of services, including prescription medicines, created by the use of medical management or cost containment measures. Most importantly, for both the state and for patients, the report should analyze the impact on utilization of services, quality of care, and patient outcomes.

**8) What is your organization's preliminary anticipation of how it might participate in coordinated care?**

PhRMA does not plan to participate directly in a coordinated care model since we are a trade association and are not involved in delivering care. However, as the pharmaceutical industry trade association, we would work with other stakeholders to ensure that coordinated care means that there are a broad range of services available to the Medicaid patient. We look forward to monitoring the progress of the work on coordinated care programs in Illinois for the Medicaid population and are happy to answer any questions.

Again, we appreciate the opportunity to comment on the policy issues associated with the creation of the Illinois coordinated care program. We look forward to monitoring this process and offering constructive suggestions when possible. We would be happy to meet and discuss any of the issues contained in these comments.

Sincerely,  
Patrick Stone  
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PhRMA