VIA ELECTRONIC FILING TO: hfs.webmaster@illinois.gov

July 1, 2011

Illinois Department of Healthcare
and Family Services
201 South Grand Avenue East
Springfield, IL 62763-0002

Re: HFS June 2011 Coordinated Care Program Key Policy Issues

Pfizer appreciates the opportunity to comment on Healthcare and Family Services (HFS) June 2011 solicitation for comments regarding the "Coordinated Care Program key Policy Issues" document. Illinois Medicaid, with its current care coordination model and pharmacy structure, has been a reasonably strong model for patient access, safety, and adherence to much needed medicines. Across payers and across states, Pfizer has experience with virtually all care coordination models. One of the primary lessons learned is that whichever care coordination model is constructed in the abstract, patient access, safety and adherence are common threads of a fundamental operating infrastructure that translate a care coordination model into real results for patients and payers.

The most important consideration in examining care coordination alternatives is that the pressure to control costs does not compromise the quality and access to care for patients who are some of the most vulnerable populations in the state. While tweaking the current model or considering different models have the potential to improve care coordination, a significant risk is associated with shifts to a different model and the implications of the shift with respect to patient access to medications.

We appreciate the thoughtful white paper that HFS has put together for comment. We will focus on the question/sections that, in our experience, warrant the most attention for patients that we know the most about. A question in the white paper that is stated "*How should consumer rights and continuity of care be protected*?" is particularly noteworthy. For the purposes of our response, we will re-phrase this question to "*how should patient access be protected*?"

Our comments with respect to this will mainly fall in the following areas:

- Access to Drug Therapies in Care Coordination Models
- Prior Authorization Requests and Utilization Management

- Special Drug Classes and Formulary Changes

- Value Added Services that Promote Healthy Lifestyles and Improved Health Outcomes

Access to drug therapies in Care Coordination Models
Advocates and some statutory precedent indicate that the prescription drug formularies in certain care coordination models are often more restrictive than those used in fee-for-service Medicaid, making access to appropriate medications a potential issue. In some cases, providers, state legislators and advocates have raised concerns that a shift from fee-for-service to managed care will restrict beneficiary access to prescription drugs. Anecdotal evidence and several studies suggest that risk based managed care organizations, for example, are more restrictive with respect to access. It will therefore be critically important to set up appropriate protections in advance and monitor for any negative consequences of the carve-in for access to medications.

Prior Authorization Requests and Utilization Management
Regardless of the model that is chosen, patient access to medications is closely tied to prior authorization requests and utilization management. With respect to the paper's question, "*Where, if at all, should HFS provide some kind of umbrella coverage for entities, e.g. negotiate a master pharmaceutical contract that would be available to all coordinated care entities*?"; we believe that the state should support policies that adhere to the Medicaid program's current standards for adjudication of prior authorization requests, and care coordination entities should use the same submission process and clinical standards, in order to help providers and patients more easily navigate the system and to promote appropriate access to therapies. We also believe that formularies should be developed and reviewed by an independent pharmacy and therapeutics committee (P&T). A majority of the members of the P&T committee should be practicing physicians, practicing pharmacists, or both, who are licensed in the state. Standards should assure that P&T committee members come from various clinical specialties that adequately represent the needs of plans beneficiaries, including an adequate number of high-volume specialists, and that specialists with expertise in a specific therapeutic area participate in formulary decisions regarding each therapeutic area. Moreover, P&T committees should meet on a regular basis (not less frequently than a quarterly basis); have a transparent process for formulary development. The P&T Committee should base its clinical decisions on the strength of scientific evidence, standards of practice, and nationally accepted treatment guidelines.

Too often, payers do not monitor their vendors carefully. To the extent that an active P&T committee must review formulary management activities, such as prior authorization, step therapy, quantity limitations, generic substitutions, and other drug utilization activities for clinical appropriateness, this will help with quality and access for patients.

In order to prevent inappropriate barriers to medication access, the HFS should ensure that there are mechanisms to allow providers to override "fail first" policies or step therapy programs that try to control costs by requiring patients to fail on a less costly medication first, especially in cases where the use of these strategies would hurt the health of a patient by interrupting or preventing needed treatment.

Special Drug Classes and Formulary Changes

Back to the question of protecting patient access, the state should establish protected "classes of clinical concern." These drugs should be essentially free from access restrictions and formularies should cover "all or substantially all" drugs in the classes. Illinois has a strong record of protecting the most vulnerable patients and this record should continue. Medicare Part D is a reasonable reference point and where formularies are required to cover "all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes." Patients who rely on these drugs need to have stable, ongoing access to them. In addition, medications that are given as an adjunct to patient therapy using the previously mentioned medications should be made available in a similar manner, such as the use of anti-emetics needed for antineoplastic therapy.

Except for newly approved drugs, the HFS should limit formulary changes to once a year, and require advance notice of 90 days to providers, patients, and manufacturers of prescription drugs being removed from the formulary. This helps avoid confusion among providers and patients that need to request an exception. In the event that a patient was taking the medication prior to removal from a plan formulary, the medication should be grandfathered for the patient to avoid an inappropriate disruption in therapy.

Value Added Services that Promote Healthy Lifestyles and Improved Health Outcomes

With respect to the paper's question, "*what structural characteristics should be required for new models of coordinated care*?"; HFS should require plans to maintain coverage of preventive and wellness services and products. As a benchmark, services and treatments that are listed by the U.S. Preventive Services Task Force with an "A" or "B" rating or immunization recommendations from the Advisory Committee on Immunization Practices at the Centers for Disease Control and Prevention should be included. Such efforts will assist in keeping more costly conditions from developing. Smoking cessation should continue to be a prioritized benefit given the documented significant costs of smoking on morbidity, mortality, and costs to the Illinois Medicaid program. The benefit should include the major features as recommended in the Public Health Service clinical practice guideline, Treating Tobacco Use and Dependence: 2008 Update (available at http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf).

E-Prescribing and Quality

With respect to the paper's question, "*to what extent should electronic information capabilities be required*?"; in the event that e-prescribing is used in the plan, care coordination entities should allow for immediate adjudication of claims. To the extent that electronic medical records and electronic prescribing systems are implemented in the state for the program by the plans, such programs should be required to allow for electronic prior authorization procedures that are receptive to real-time adjudication of such requests. In the event that a prior authorization request is denied, information about the reason for the denial and specific information about acceptable reasons to grant approval must be provided to the prescriber.

With respect to the paper's question, "*what should be appropriate measures for health care outcomes and evidence-based practices*?"; the 2010 report The State of Health Care Quality from the National Committee for Quality Assurance (available at http://www.ncqa.org/tabid/836/Default.aspx) is a good starting point.

We realize that like many states, Illinois faces significant budget pressures and that containing costs where possible is and will remain an urgent priority. If a new care coordination model is put in place, it should be done in such a way that it does not generate other unanticipated costs in the health system or threaten access to needed medications. We strongly believe that it is important to ensure that safeguards are in place to make certain that physicians continue to be empowered to provide the best possible care to patients, and that patients' access to lifesaving and life-improving medicines is protected.

Thank you for your consideration. Please let us know if you would like to discuss any of these issues or have any questions.

Sincerely,

Julie Mirostaw
Director, Government Relations