Iowa Osteopathic Medical Association

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October 21, 2009

To: Iowa Legislators, the Iowa Department of Public Health and interested others

Subject: Prescription Medication Usage Study

During the past legislative session, Senator Jack Hatch introduced Senate File 389 which set three broad objectives for healthcare in Iowa; to improve the quality, access and affordability of the healthcare provided to all Iowans. Division VI of the bill as introduced included a dramatic expansion of the scope of practice of pharmacists by permitting pharmacists to practice Medication Therapy Management.

The Iowa Osteopathic Medical Association (IOMA) agrees with and is supportive of the goals of improving the quality, accessibility and affordability of healthcare in Iowa. Keeping these objectives in mind, any change in the practice act of any healthcare provider should in some way move Iowa closer to meeting these goals.

In our opinion, Medication Therapy Management fails to move Iowa closer to any of these goals.

Medication Therapy Management does not improve quality. In 2000, the Iowa Legislature commissioned the University of Iowa, School of Pharmacy to conduct a study on Medication Therapy Management. During the 2003 session, the report of the findings of the study was presented to the Legislature. One of the many findings of this study was that there was no quality improvement associated with Medication Therapy Management services. The study report stated that there was no *"statistically significant difference between those who received (Medication Therapy Management) vs. those who did not in the pattern of monthly HCFA 1500 charges over time."* In other words, patients receiving Medication Therapy Management services went to the physician's office, the emergency room and were hospitalized at the same rate as patients who did not receive the service.

Other studies have been done which purport to show quality improvements for those receiving Medication Therapy Management services. However, these studies have looked only at the in-patient setting or at highly selected populations. The findings of these studies cannot be extrapolated to the general population.

Medication Therapy Management does not improve access. On the surface it would seem that increasing the number of providers available to patients should increase access. However, after cross referencing data from the multiple public sources, we found that there was not a single Iowa community with a pharmacy that did not also have a healthcare clinic. In other words, if a patient can get to a pharmacy, they can get to a medical clinic.

Medication Therapy Management does not improve cost effectiveness. In the same 2003 study provided to the legislature, the authors concluded, *"After adjusting for age and gender, (Medication Therapy Management) services had no significant effect on the net number of medications or medication charges"*. This despite the fact that the study focused on the sickest 4% of patients. A population with high drug utilization and chosen because it was felt this population would benefit most from this service. As noted above, patients receiving Medication Therapy Management services also had the same hospital, emergency room, and physician utilization as patients not receiving the service. In short, the study showed that despite the state spending significant funds on providing the service, it had no impact on decreasing the cost of medication therapy.

In summary, Medication Therapy Management has not been shown to achieve any of the goals of providing Iowans with improved quality, more affordable, or accessible healthcare. As such we urge you to reject the concept of Medication Therapy Management.

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COPY

March 3, 2003

To: Iowa Legislators, the Iowa Department of Human Services, and interested others

Subject: The Iowa Medicaid Pharmaceutical Case Management Program Evaluation

As our knowledge of disease and its treatment continues to grow, the possibility of medical errors also increases. To address this concern, new methods of providing care have been proposed. Any system of care that has the potential to reduce medical errors, improve patient health outcomes, or reduce healthcare costs is worthy of study. But before any new care system is implemented, it is our belief that it must be thoroughly evaluated for its impact on healthcare costs, its feasibility, and most importantly on patient safety.

The members of the Iowa Osteopathic Medical Association (IOMA) are committed to providing Iowans the highest quality care possible. We recognize that there are many professionals who provide care to the citizens of Iowa and that each profession has a role in the care of patients. It is our firm belief however, that all professionals should make available only those services for which they have sufficient education, training and skill, and the statutory authority to provide.

The final report for the Iowa Medicaid Pharmaceutical Case Management (PCM) Program was recently submitted to the Legislature. IOMA has been intimately involved in this study since its inception. Kevin de Regnier, DO, Past President of the Association, was a member of the project Advisory Panel.[1] Throughout the study design process, IOMA raised concerns regarding the study design and the possibility that the project would not provide real world results.[2]

The final report of the study investigators has now been presented. After a thorough review and analysis of their findings, we find that we must respectfully disagree with the conclusions of the study authors. Attached herewith are our comments on the findings of the report for the PCM Program.

Overview

IOMA has the following general comments regarding the Medicaid PCM study report:

1. **The study failed to show a cost savings to the Medicaid program.**
2. **The study investigators had a vested interest in the outcome of the study and therefore the study report must be evaluated in the light of possible investigator bias.**
3. **The study subject, pharmaceutical case management was never defined. Thus the study does not reflect the results of providing a specific or standardized method of care.**
4. **Many of the evaluation tools utilized in the study to measure outcomes were subjective.**
5. **The conclusion of the study authors is contradicted by the data presented.**
6. **The reimbursement provided to study participants was unrealistically high. In light of the Medicaid budget problems, sustaining these reimbursement levels is not possible and thus calls into question the willingness of physicians and pharmacists to continue to provide the service under real world reimbursement rates.**
7. **Only "high risk" patients participated in the study. These patients comprise only 4% of the Medicaid population. Therefore, study results cannot be generalized to the entire Medicaid population or program.**

In addition to our concerns about the study report, we have the following general concerns about pharmaceutical case management:

1. **Most community pharmacists lack adequate education and training to conduct PCM.**
2. **Most community pharmacies lack the necessary facilities to provide PCM.**
3. **PCM fragments care increasing the possibility of error.**
4. **PCM requires patients with limited resources to find transportation to two appointments.**
5. **Under current practices, pharmacists do not have access to information contained in the patient's medical record. This increases the possibility of medical errors.**

Discussion

1. **The study failed to demonstrate a cost savings to the Medicaid program**

According to the study protocol, the authors anticipated saving $56.00 per recipient per year.[3] In the final report, the authors cite other studies that have shown cost savings ranging from $122 to $856.[4] It should be noted that this is per recipient regardless of severity of illness. Even focusing on the sickest 4% of the Medicaid population, the study failed to demonstrate any savings. According to the study authors, "After adjusting for age and gender, PCM services had no significant effect on the net number of medications or medication charges.[5]

2. **The study investigators had a vested interest in the outcome of the study and therefore the study report must be evaluated in the light of possible investigator bias.**

From the beginning of the project, investigators have referred to PCM as a "new service" under the Medicaid program.[6] The enabling legislation, HF 760 78th General Assembly, clearly indicates that the intent of the Legislature was to authorize a study only.[7]

The Iowa Pharmacy Association (IPA) was intimately involved in the study design, implementation, evaluation and report of the study. While it is certainly appropriate for all professions involved in the study to have a voice in the process, the IPA was far more involved than other professions. The original protocol was developed with input only from the IPA. [8] Only after the investigators received complaints from IOMA and the Iowa Medical Society (IMS) was the Advisory Board opened to physicians. All general meetings of the Advisory Board were held at the IPA offices. Correspondence regarding the study design and implementation was received on IPA letterhead stationary[9] and e-mails bore an IPA sender e-mail address.[10] All of this points to the IPA as being intimately involved in the entire study process.

In evaluating the effects of PCM the investigators conducted in-person interviews with pharmacists but not physicians and held large group discussions with pharmacists but not physicians at the Annual Meeting of the IPA.[11] The only solicitation of physician opinion was a survey faxed to 70 physicians at the end of the study.[12]

One of the purposes of a professional association such as the IPA is to promote the profession it represents. One of the findings of the study was that the most common recommendation of the pharmacist was to start a new medication[13], a product that would likely generate additional sales and profits for the pharmacist. But for a study to yield reliable and credible results, the investigators must be free of bias. It is clear that the IPA, which rightly has as its goal the promotion of the profession of pharmacists, was deeply involved in this study and thus the question of investigator bias must be raised.

3. **The study subject, pharmaceutical case management was never defined. Thus the study does not reflect the results of providing a specific or standardized method of care.**

The study protocol states that one of the specific objectives of the study would be "to describe the care provided by reimbursed pharmaceutical care providers".[14] Both IOMA and IMS raised the concern that no definition of PCM had been established prior to the study implementation. It is our opinion that it is not possible to study something that hasn't been defined. While the study investigators collected data on the services provided[15], there was never any specific protocol designated for pharmacists to follow. Thus the care provided to patients varied widely from pharmacist to pharmacist.[16] With no uniformity in the service provided, it is not possible to determine if the study results reflect the results that could be expected if PCM became common practice.

4. **Many of the evaluation tools utilized in the study to measure outcomes were subjective.**

While some data collection activities included objective measures, most did not.[17] Of the seven study objectives, six relied in whole or in part on subjective measure to determine outcomes. Thus study investigators drew conclusions that aren't supported by objective unbiased measurements. For example, the Medication Appropriateness Index relied upon heavily to measure the clinical impact of PCM, requires the opinion of the person completing the tool in 8 of the 10 measures.[18] One of the main reasons for the subjectivity of this index is the pharmacist's inability to access and evaluate the patient's complete medical record. For instance, one of the measures of the MAI is "is there an indication for the drug". Without the complete medical record, it is impossible to objectively evaluate this measure. Likewise, "is the dosage correct" is subject to opinion, especially if the pharmacist lacks the entire medical record. Many drugs have several uses and the dosage for each use is different. If the pharmacist incorrectly assumes a drug is being used for a particular indication, the dose may appear inappropriate.

The reliance on subjective measures is sometimes necessary when no objective measurement tool is available. But when subjective measures are the basis for conclusions, those conclusions must be viewed in light of the potential bias inherent in subjective measurements.

5. **The conclusion of the study authors is contradicted by the data presented.**

In the executive summary of the study findings, the authors state, "PCM Services were provided to many eligible patients."[19] This statement is contradicted just two paragraphs later when the authors state that only 943 of 3,037 eligible patients received services in the first year of the program.[19] The study authors also conclude, "The data suggested that emergency room and outpatient facility utilization may have decreased for patients of pharmacies that adopted PCM more intensely."[20] Yet in their discussion of the study results, the authors state, "Health status, healthcare utilization, and patient satisfaction were secondary endpoints in this study. They were measured for descriptive purposes only and it was known that the study would have insufficient power to detect small improvements in these measures."[21] The data presented shows that there was no "statistically significant difference between those who received PCM vs. those who did not in the pattern of monthly HCFA 1500 charges over time."[22]

6. **The reimbursement provided to study participants was unrealistically high. In light of the Medicaid budget problems, sustaining these reimbursement levels is not possible and thus calls into question the willingness of physicians and pharmacists to continue to provide the service under real world reimbursement rates.**

The reimbursement provided for services rendered during the study was unrealistically high. Both the physician and pharmacist were paid $75.00, or a total of $150.00, for an initial patient assessment.[23] Additional payments were made for follow-up care and assessments of new problems. This is nearly 5 times the payment received by the physician for a typical office visit. We are deeply concerned that this reimbursement rate was a strong inducement for both

physicians and pharmacists to participate in the study. If the program is to continue, these reimbursement rates are unsustainable and must be adjusted to fit within the current Medicaid payment schedule. It is our opinion that doing so would significantly reduce reimbursement levels. This would obviously impact the willingness of both physicians and pharmacists to participate in the program and thus further reduce the effectiveness of PCM.

7. **Only "high risk" patients participated in the study. These patients comprise only 4% of the Medicaid population. Therefore, study results cannot be generalized to the entire Medicaid population or program.**

Investigators chose to focus the study on those patients at highest risk for medication errors. It was logical that PCM would have the largest impact in this group and thus provide the best opportunity for measurable outcomes. This patient population represents just 4% of the total Medicaid patient population. As noted these patients were selected to give the greatest opportunity to measure a change in outcomes. If the program were expanded to include all Medicaid patients, the effectiveness would significantly decrease.

General PCM Concerns

It is our belief that before any new care system is implemented, it must be thoroughly evaluated for its impact on; healthcare costs, its feasibility, and most importantly, patient safety. With these beliefs as our basis, we have the following general concerns regarding PCM.

1. **Most community pharmacists lack adequate education and training to conduct PCM.**

In order to participate in the PCM, pharmacists and pharmacies had to meet specific criteria. These included completion of professional training regarding patient-oriented medication-related problem prevention and resolution. They must have a private consultation area in the pharmacy, maintain longitudinal problem-oriented patient records and had to submit five of those records for review. The training that pharmacist were required to take before participation was extensive. It included training in; practice site re-engineering, patient data collection, drug therapy problem prevention processes, clinical problem solving, implementation of a problem-oriented patient record, communication skills, and clinical use of drug information sources.[24]

Very few Iowa pharmacists have had this type of training. It is only in the last few years that this training has been integrated into the curriculum of pharmacy colleges. It will be some time before a significant number of trained pharmacists are available in Iowa.

2. **Most community pharmacies lack the necessary facilities to provide PCM.**

As noted above, one of the requirements needed to provide PCM services is a private consultation area. Patients deserve privacy. They need to know that conversations in which they discuss private personal and medical issues are confidential. This can only be done when a private enclosed area is available. Most retail pharmacies in Iowa lack such facilities. Patients

should not be expected to divulge such private information when the possibility of being overheard exists.

3. PCM fragments care increasing the possibility of error.

PCM increases the number of people involved in the patients care. On the surface this may seem like a good thing. Providing a system of checks and balances. But in fact the fragmentation of care that is created by PCM increases the likelihood of errors.

In the current healthcare system, a patient is seen by his or her physician who conducts a history of the patient's complaint, conducts a physical examination, orders and interprets laboratory and other tests, formulates a diagnosis and prescribes a course of therapy. In addition, the physician has within the medical record, a complete history of the patients past health problems. The only information the pharmacist receives is the prescription. The pharmacist has no education, training or skill in diagnosing disease and therefore information other than the prescription is of no use to him or her.

When the physician establishes a diagnosis, he/she explains the diagnosis and the treatment plan to the patient. The patient then goes to the pharmacy to have the prescription filled. The pharmacist fills the prescription, giving the patient additional medication related information as needed.

Under the PCM concept, the patient would proceed as above but would also meet with the pharmacist independent of a physician prescription. The pharmacist would review all of the patients diagnosis as reported by the patient, review patient medications, and recommend changes in therapy. This may or may not agree with what the physician has told the patient. The pharmacist does not have access to the patient's medical record that may contain information that would change the pharmacist's recommendation if he/she were aware of it. The end result is that patients become confused, causing them to either give up on needed therapy or place additional calls to the physician's office. Of course all of this assumes that patients see the same physician and get their prescriptions from the same pharmacist.

In this model, care is not enhanced; rather it is fragmented and leads to patient confusion and an increased risk of medical errors.

4. PCM requires patients with limited resources to find transportation to two appointments.

PCM contemplates that patients will visit the pharmacist on at least 4 occasions during a year. These visits would take more time than it is possible to provide during a routine prescription filling. Thus a separate specifically scheduled visit would be required. For a patient that is financially struggling, this means additional travel expense. Either due to use of their private vehicle or because of the need to use alternative transportation such as buses or taxis. In rural areas, these resources may not be available.

5. **Under current practices, pharmacists do not have access to information contained in the patient's medical record. This increases the possibility of medical errors.**

As we have previously noted, the patient's medical record is not currently accessible to the pharmacist. This lack of information increases the likelihood that the pharmacist will make a recommendation without the full knowledge of the patient's condition. Thus PCM increases the risk of the very thing it is trying to avoid -- medical errors.

Summary

Based on the criteria set forth in the study protocol, the PCM project demonstrated that PCM as performed in this study; failed to reduce pharmaceutical costs, failed to improve health outcomes, and was provided in an artificially enriched financial environment. In light of the findings of this study, to implement PCM at this time would be ill advised.

IOMA stands ready to work with all healthcare providers in the continuous search for new and innovative ways to provide healthcare services to the citizens of Iowa. Before implementing any new system of care, Iowans must know that that system has been fully evaluated through scientifically valid studies and found to be an improvement over the healthcare methods currently in place.

[1] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 15. 2002

[2] IOMA. Letter dated October 23, 1998

[3] Iowa Medicaid Pharmaceutical Care Reimbursement Pilot Project Study Protocol. Pg 3. 1998

[4] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 13. 2002

[5] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 47. 2002

[6] Study Advisory Board. Introductory letter to pharmacists and physicians. 1999

[7] HF 760 78th Iowa General Assembly.

[8] Clarke, Iowa Pharmacy Association, Letter to IOMA, 1998

[9] Clarke, Iowa Pharmacy Association, Letter to IOMA, 1998

[10] CClarke@iarx.org. Pharmaceutical Case Management Update. E-mail. 2000

[11] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 58. 2002

[12] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 68. 2002

[13] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 9. 2002

[14] Iowa Medicaid Pharmaceutical Care Reimbursement Pilot Project Study Protocol. Pg 3. 1998.

[15] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 19. 2002

[16] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, pages 26-38. 2002

[17] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 18. 2002

[18] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 39. 2002

[19] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 8. 2002

[20] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 9. 2002

[21] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 70. 2002

[22] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 54. 2002

[23] Chrischilles, E. Iowa Medicaid Pharmaceutical Case Management Program Final Report, page 12. 2002

[24] Iowa Medicaid Pharmaceutical Care Reimbursement Pilot Project Study Protocol. Supplement. 1998.