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General Comment

RE: CMS-4140-IFC

Please see first attachment for comments.

Second attachment is supporting documentation.

RE: CMS-4140-IFC

If mental health parity is to achieve the goal of improving mental health treatment for the majority of individuals experiencing mental health issues, then it must not only allow, but encourage evidence-based treatment to address the lack of quality care for those patients receiving mental health treatment in the general medical setting. As the Interim Final Rules point out, many individuals are seeking care for mental health issues in the general medical setting, with the vast majority not receiving adequate care (more than 83 percent did not receive minimally adequate care per the study cited in the Rules). Apparently, the agencies writing the Interim Final Rules recognized this issue and included language to allow for variations of the restrictions imposed on nonquantitative treatment limitations based on clinically appropriate standards of care. Just as evidence-based medicine will lead to improved health and outcomes for medical procedures, the same review and plan designs based on clinical guidelines should be applied to mental health treatment that is delivered in the general medical setting.

The attached article, "Improving Treatment Outcomes through Drug Interventions," that is published in the 2nd Quarter 2010, Journal of Employee Assistance, presents a proven program (with a case study) for dramatically improving treatment outcomes for mental health treatment delivered in the general medical setting through an evidence-based intervention. The intervention, called the Pharmacy Intervention Protocol (PIP), utilizes clinically appropriate standards of care for mental health treatment that are not usually applied within the general medical setting. To be successful, it utilizes a financial motivator to motivate behavior change, just as with evidence-based review for medical procedures that are deemed to not be clinically appropriate. Key to note, PIP only focuses on patients receiving mental health treatment from non-psychiatrists, which is well documented to result in suboptimal care for most. Furthermore, it only targets those psychotropic drugs that are primarily prescribed in the general medical setting, where appropriate clinical guidelines are most likely not being applied.

What needs to be clarified in the Final Rules is the procedure for a clinically proven intervention like PIP to be allowed under the Final Rules based on the exception that recognized clinically appropriate standards of care may permit a difference. PIP is currently improving the care and outcomes for many patients while reducing their costs (and the costs to their employers) as a result of applying appropriate clinical guidelines. Those employers are now realizing better mental health services and outcomes for many of their members. This is leading to reduced costs in numerous areas and those employers do not want to take a step back whereby many of their employees and dependents will once again not receive optimum care.

The result of the creation of PIP is a proactive evidence-based population management program for individuals seeking mental health care in the general medical setting. Furthermore, numerous studies have clearly documented the lack of quality mental health treatment in the general medical setting (as stated in the attached article). Certainly, any

health plan would have a review process in place for a course of medical treatment that studies reported less than 13 percent of patients were receiving minimally adequate care from a type of provider.

Beyond parity, the bigger picture is overall healthcare reform. As the administration has put forth, evidence-based treatment is one of the real solutions to many of our healthcare problems, and mental health must be included in that process. How much is the public sector spending towards lack of appropriate care for mental health? How much could be saved in the public sector by implementing evidence-based treatment for the millions of individuals dealing with mental health issues? The first step is continued use of this solution in the private sector, and then expansion into the public sector.

Improving Treatment Outcomes through Drug Interventions

Many people with mental health conditions receive care in general medical settings. EAPs can help improve their treatment and decrease symptoms.

by Fred Newman

Although many people assume that the increasing prescription of antidepressants and certain other psychotropic drugs is a positive trend and reflects the fact that more people are seeking treatment for depression and other mental health conditions, the reality is that most mental health patients today are receiving sub-optimal care. As the use of these drugs has increased over the past decade, the percentage of patients with behavioral health issues being seen by mental health professionals has decreased, not increased.

The regulations that were developed to implement the Mental Health Parity and Addiction Equity Act of 2008 outline this problem. The regulations reference a study that found that only 12.7 percent of individuals received minimally adequate mental health treatment in general medical settings. Unfortunately, the regulations do not address the root cause of this problem: a lack of access to appropriate mental health care in the early stages of the condition.

Most psychiatrists have full patient loads and do not have the capacity to expand their practices to handle more patients (many are already unable to spend the time necessary to appropriately treat the patients they currently have). Therefore, the majority of mental health care will continue to be provided within general medical settings for the foreseeable future. This will lead to or exacerbate the following quality issues:

- Lack of quality assessments of mental health problems;
- Lack of ongoing screenings to evaluate the effectiveness of treatments;
- Lack of medication management;
- Lack of patient education about the condition(s) being treated;
- Lack of psychotherapy for those dealing with mental health stressors; and
- Lack of feedback to patients regarding improvement in their condition.

Individuals who face stressors they cannot manage will typically receive prescriptions for antidepressants from a non-psychiatrist. But without combining short-term psychotherapy with their drug therapy, only the symptoms of their condition will be treated.

Moreover, because most medical doctors receive little or no training in psychiatry, they often are not aware of the withdrawal symptoms associated with stopping the use of antidepressants too quickly. What seems like a relapse of a depressive disorder may in fact be a withdrawal symptom resulting from the patient not properly tapering (reducing the dosage of) the drug. This can lead to a recommendation of long-term drug therapy when it may not be appropriate.

THE SOLUTION? EAPS

EAPs are in a unique position to address this lack of quality treatment. Studies report that if patients receive appropriate treatment within the first six months of the onset of a depressive disorder, they have better than a 50 percent probability of achieving remission. If they do not receive appropriate treatment until one year after the onset, the odds of remission drop to less than 20 percent.

The majority of depressed patients receiving care within general medical settings will experience worsening symptoms.

Thus, it is imperative that individuals dealing with depression engage in screenings and treatment modifications as soon as possible based on their medical history and scoring of symptoms. Influencing these individuals to take such actions requires innovative programs that encourage participation in results-oriented treatment solutions.

My company, Interface EAP, developed such a program in 2004. The program, known as Pharmacy Intervention Protocol (PIP),* has proven to improve outcomes and reduce costs. The key components of PIP are as follows:

- A two-way secure data feed to the pharmacy benefit manager (PBM) to exchange drug and compliance information;
- Filtering of drug data from the PBM, using proprietary software;
- Outreach to potential candidates based on filtering of drug data;
- Financial incentives involving drug co-pays to encourage greater

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participation;

- Telephonic screenings to determine candidates for participation;
- Daily electronic reporting of compliance/noncompliance to the PBM;
- Outreach to and partnering with prescribing physicians to improve treatment outcomes;
- Results of ongoing standardized screenings provided to patients and physicians;
- Educational materials provided to patients so they better understand the conditions for which they are being treated;
- Recommendations for medication management and other treatment modifications based on screening outcomes and treatment history;
- Coordination with the EAP for short-term psychotherapy when appropriate;
- Outcome reporting on quality improvement and cost savings; and
- Compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Americans with Disability Act (ADA) per established legal opinions.

PIP CASE STUDY

On June 15, 2009, Interface EAP and Aetna completed an initial outcome study reviewing medical claims costs across two years of data for workers covered under a self-funded health plan provided by an Arizona hospital system. The purpose was to evaluate overall medical claims costs and other data resulting from PIP.

The study looked at plan members who filled prescriptions for predetermined target drugs, which were identified from the plan's drug data. Every two weeks, PIP received drug data from the PBM (Express Scripts) through the plan administrator (Schaller/Anderson–Aetna). Based on defined criteria, the drug data were filtered by Interface EAP to identify plan members as potential PIP candidates.

A financial motivator was used by the health plan to encourage candidates to complete a telephonic screening. If a plan member did not complete the screening, his/her co-pay for this group of drugs was doubled; if a plan member completed the screening but chose not to participate in PIP, his/her co-pay was doubled. Those who completed the screening and participated in PIP for up to 18 months received prescriptions at the normal co-pay level. If a member did not complete the program, his/her co-pay was doubled.

Using this process, PIP identified a compliant group and a noncompliant group by unique member ID. The compliant group was defined as plan members who had filled a target prescription, completed the screening, participated in the protocol for the required time period, and were covered by the health plan for both 12 months prior to the intervention date and 12 months after the intervention date.

The noncompliant group was defined as plan members who had filled a target prescription but failed to complete the screening, declined participation after completing the screening, or

Mental Health Care: What the Media are Saying

"A significant proportion of individuals with behavioral health problems are treated exclusively in the general medical setting, which has become the de-facto mental healthcare system...significant quality problems have been found with general medical providers' screening, treatment, and monitoring practices."

"An Employer's Guide To Behavioral Health Services," National Business Group on Health, 2005

"Although access to psychotropic medications is available due to non-psychiatrists' prescriptions, concerns remain that patients still receive treatment in accordance with evidence-based guidelines, psychotherapy, adequate medication monitoring, and appropriate intensity of treatment."

An article in Open Minds *on September 24, 2009, reporting on a study in which researchers reviewed 472,173 prescriptions filled between August 2006 and July 2007 from the IMS National Prescription Audit Plus database. The researchers reported that 79 percent of prescriptions for antidepressants were written by non-psychiatrists and 87 percent of prescriptions for anxiolytics were written by non-psychiatrists.*

"The effectiveness of a dozen popular antidepressants has been exaggerated by selective publication of favorable results."

"... doctors unaware of the unpublished data are making inappropriate prescribing decisions that are not in the best interest of their patients."

"There is a view that these drugs are effective all the time ... I would say they only work 40 percent to 50 percent of the time based on reviews of the research at the FDA."

Excerpts from a January 17, 2008, Wall Street Journal *article regarding a review published the same week in* The New England Journal of Medicine.

"More Americans are being prescribed multiple psychiatric medications for use at the same time, but most people diagnosed with recent depression don't get adequate treatment, according to two independent studies published Monday."

"Studies: Mental Ills Are Often Overtreated Or Undertreated," Wall Street Journal*, January 5, 2010*

"There is little evidence to suggest that (antidepressants) produce specific pharmacological benefit for the majority of patients with less severe acute depression," researchers wrote.

Excerpt from a January 6, 2010, Wall Street Journal *article regarding a study published the same week in* The New England Journal of Medicine.

dropped from the protocol prior to completion. Like the members of the compliant group, they must have been covered by the health plan for both 12 months prior to the intervention date and 12 months after the intervention date.

The intervention date was defined as the date that a compliant group member began participating in PIP or the date a noncompliant group member was reported noncompliant to the PBM. For purposes of the study, the health plan administrator reported medical claims data by member ID for the year prior to the intervention date and the year after.

For the 24-month period, the following results were reported:

- **Compliant Group** (142 members): A decrease in average annual claims costs of $5,674 per plan member, or a 29.4 percent overall decrease in claims costs for the year after the intervention date versus the year before the intervention date.
- **Noncompliant Group** (272 members): An increase in average annual claims costs of $16 per member, or a 0.1 percent overall increase in claims costs for the year after the intervention date versus the year before the intervention date.

In addition, the following outcomes were reported:

- Nearly two-thirds (63 percent) of members who had completed multiple standardized screenings scored a reduction in their symptoms within the first 15 months of the program.
- EAP utilization increased to an annual average of 21 percent in the first year of PIP. In the years before PIP was introduced, the annual average EAP utilization rate was 5 percent. For the second year of PIP, annual EAP utilization was 14.8 percent, a significant increase in utilization over the years prior to PIP.
- Drug spending for the target drugs declined by 30 percent within 15 months of the start of PIP as calculated on a per employee, per month (pepm) basis. Documented reduced drug spending exceeded the pepm cost of PIP by 59 percent.

BECOMING THE GATEWAY

It is a clinical fact that depression, if not properly treated, will worsen and become more resistant to treatment. Therefore, the majority of depressed patients receiving care within general medical settings will experience worsening symptoms and, once exposed to direct consumer marketing by psychiatric facilities, will encounter more restrictive and costly levels of care. Expanded mental health benefits under the new health insurance parity law will only magnify the cost impact to employers.

EAPs can become the gateway to early treatment and help reduce the number of chronic patients. Through a program like PIP, EAPs can use their assessment and counseling resources to bridge the gap in quality care.

Although the parity law regulations generally prohibit imposing any nonquantitative treatment limits on mental health or substance use disorders that are not also applied to medical/surgical benefits in the same classification, they do allow for variations to the extent that recognized clinically appropriate standards of care may permit a difference. Therefore, the regulations should permit a difference in drug plan design for PIP, since it applies clinically appropriate standards of care not utilized in the general medical setting to achieve significant outcome improvements. For example, the study presented in the regulations reported that only 12.7 percent of individuals treated in general medical settings received minimally adequate mental health care, while 63 percent of PIP members seeking mental health treatment in general medical settings reduced their symptoms.

It is only logical for EAPs to evolve into population management roles for mental health, given the current lack of quality treatment for so many. The total cost of not properly treating mental health issues extends to increased medical claims, increased disability claims, and reduced productivity (as the regulations also report). ■

** Patent pending*