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To: Clients and Friends
From: John Gorman and Jean LeMasurier
Date: September 18, 2008
Re: Gorman Health Group Summary of MIPPA Regulations Released 9/15/08

On September 15, 2008, CMS issued two regulations to implement the provisions in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Because many of these provisions were also included in the May 16, 2008 Notice of Proposed Rulemaking (NPRM), these new regulations take into account the public comments that were submitted in response to the Notice of Proposed Rulemaking.

The following is a non-comprehensive summary meant to draw attention to some of the critical areas and should not be considered a substitute for rigorous review of the regulations.

The first regulation, CMS 4131-F "Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions" is a final rule that includes marketing reforms that CMS wanted to make effective before the fall marketing campaign begins on October 1, 2008.

The second regulation is an Interim Final Rule with Comment, CMS 4138-IFC, "Revisions to the Medicare Advantage and Prescription Drug Benefit Program". This regulation provides for a 60 day comment period; however, in the meantime, the provisions in the interim rule will take effect.

The regulation includes marketing provisions are effective November 15, 2008 as well as provisions impacting cost plans, Medicare Advantage (MA) plans, Special Needs Plans (SNPs), Private Fee for Service (PFFS) plans and Prescription Drug plans.

Other provisions from the proposed rule are not included in these final or interim final rules, e.g. marketing civil monetary penalties, Part D pass-through pricing, LIS program changes. Thus, it can be reasonably assumed that CMS will be issuing additional rules in the future.

In general, the Final and Interim Final rules incorporate the MIPPA provisions without significant interpretation. Some of the key changes are listed below:

- The IFC changes the policy on Commissions for marketing agents and brokers from the policy in the NPRM to a new policy based on public comments. The new policy is similar to the commission structure used in the general insurance industry and for Medigap (6 years with first year no more than 200% of renewal years including refunds if a beneficiary disenrolls during the first 3 months). The rule allow plans flexibility to set the rates.
- The Final rule clarifies the policy on the prohibition on unsolicited contact to allow direct mail, but does not allow plans to follow-up a mailing or event or to contact a current or former member without a specific beneficiary request.
- The Final rule does not include a federal pre-emption of the appointment fees as proposed in the NPRM.
- Guidance on the provision in the IFC requiring agent and broker testing raises the standard for a passing test score from 80% to 85%.
- The IFC provision on the marketing scope of appointment clarifies that either the request must be documented in writing by the beneficiary or must be recorded.
- The Final rule requirement that eliminates the marketing file and use eligibility process means that some plans will need to convert to file and use certification.
- The IFC clarifies how SNPs can meet the new MIPPA requirements for a comprehensive risk assessment, individualized treatment plans, use of an interdisciplinary team and expands on the SNP Quality Improvement Program.
- The IFC includes minimum requirements for the Dual SNP contract with the State Medicaid agency.
- The IFC provision on PFFS networks clarifies that the market area test does not include SNPs.
- The IFC changes the eligibility criteria for the LIS using criteria for financial eligibility from the SSI program.
- Regulatory guidance strongly emphasizes both CMS and plan oversight this fall, e.g. CMS will increase secret shopping threefold.

Selected changes from the **Final Rule CMS 4131-F** include:

http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/2008-21674_PI.pdf

http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/MIPPA_Imp_memo091208_Final.pdf

Elimination of File & Use Eligibility – The final rule replaces the File & Use “Eligibility” Process with the File & Use “Certification” process. The regulatory guidance requires affected plans to submit a one-time certification form as soon as possible.

Prohibition on Unsolicited Contacts – The regulation includes the MIPPA prohibition on cold calling. The preamble of the regulation clarifies that plans may not make unsolicited outbound calls to market products to existing members, former members, and plans may not follow-up with beneficiaries who attended a sales event or to whom a direct mail was sent without specific beneficiary request.

A valid beneficiary request may include a business reply card or request to a CSR, but a telephone number is insufficient. CMS intends that the beneficiary request is limited to a specific request and does not establish an open-ended relationship with the plan for other purposes. Additionally scripts must include a privacy statement that the beneficiary is not required to provide personal information and plans are prohibited from requesting beneficiary identification numbers.

Prohibition on Cross Selling – The regulation includes the MIPPA prohibition on selling non-health products. The preamble clarifies that plans may sell non-health products on inbound calls when the beneficiary requests such information. Marketing non-health products to current members is subject to HIPAA. The regulation requests comments on a prohibition or limitation on including marketing of non-health products during hold times messages or IVR response.

Prohibition on Marketing in Health Care Settings – The regulation includes the MIPPA prohibition on marketing in health care settings. The guidance provides additional examples of restricted areas and acceptable common areas and clarifies that beneficiaries residing in long-term care facilities must request appointments.

Prohibition on Marketing at Education Events – The regulation includes the MIPPA prohibition on conducting sales activities at educational events. Guidance clarifies that materials for educational events must include a disclaimer that the event is “educational only and information regarding the plans will not be available”.

Prohibition on Provision of Meals – The regulation prohibits meals of any kind at events. Guidance clarifies that meals may not be provided or subsidized by any party at any event where plan benefits are being discussed or plan materials are being distributed. Examples are provided of the types of refreshments that may be offered.

Requirement for Licensure and State Appointment of Agents and Brokers – The final rule does not pre-empt fees connected with State appointment laws as included in the proposed rule and does not specify that plans must pay for these fees. The final rule retains the proposed policy that certain customer service activities do not require use of a State licensed representative, e.g. fulfilling a request for materials.

Selected changes from the **Interim Final Rule CMS 4138-IFC** include:

http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/2008-21686_PI.pdf

1876 Cost plans – The final rule clarifies that when a cost plan's service area encompasses more than one MSA, then the competition test would be applied in each MSA, and could have the effect of allowing only part of the service area to continue.

SNP Model of Care– The regulation modifies the proposed rule to add the three new MIPPA requirements (comprehensive risk assessment, individualized plan of care and interdisciplinary team). All SNPs will be required to demonstrate how they are meeting the requirement to use evidence based models of care and to measure the extent of evidence based care management.

The preamble and regulatory guidance provide several examples of how SNPs might accomplish this, for example, by tasking the Medical Director or medical advisory committee to monitor peer reviewed medical journals or to contract with providers who use nationally recognized clinical protocols.

SNP Comprehensive Health Risk Assessments – The preamble clarifies that the initial comprehensive risk assessment be conducted within 90 days of enrollment and annually thereafter. The preamble encourages plans to conduct the assessment more frequently than every 12 months to adjust for health status changes of a vulnerable population.

SNP Individualized Care Plan and Interdisciplinary Team – The regulations provide flexibility for the SNP to design the interdisciplinary team and treatment plan based on the unique needs of their enrolled population, provided certain essential care management elements are included (e.g. goals and objectives, measurable outcomes). SNPs are accountable for measuring the effectiveness and extent that each beneficiary's care is appropriately managed by an appropriate team.

SNP Quality Improvement Program – The regulations require SNPs to have a quality improvement program that collects and reports health outcomes and indices of quality relevant to its enrolled population and measures the effectiveness of its model of care through collecting and reporting of data that demonstrate: access to care, improvement in health status, implementation of the model of care, comprehensive risk assessment, implementation of the individualized plan of care, networks with targeted clinical expertise, delivery of services across a continuum of care, delivery of services and

benefits targeted to the vulnerable beneficiaries, use of evidence based practices, use of integrated communication systems.

The preamble clarifies that there are three tiers to the quality improvement program. The first is the information that beneficiaries will use to compare plans (e.g. collection and reporting of HEDIS and three structure and process measures which is already under way and will be expanded in the future).

The second is to customize the currently required chronic care improvement program and quality improvement projects to the unique needs of the their enrolled population drawing from data from a number of sources (e.g. claims, medical records, disease management outcomes) and using a number of health care domains (e.g. functional status, clinical outcomes, behavioral health, medication management, family/caregiver support).

The third tier is CMS analysis of SNP reported data on the effectiveness of the SNP models of care which is currently under development. CMS will review the models of care in conjunction with periodic audits; for 2010 CMS will review how plans have implemented their models of care. CMS is requesting comments on the types of monitoring data that plans should be required to submit in CY 2010.

Dual SNP Contract with State Medicaid Agency – The interim rule keeps the MIPPA language that DE SNPs must have a contract with the State Medicaid agency (although the preamble notes that states are not required to enter into contracts with plans) and provides that effective January 2010, new DE SNPs must have a state contract and existing SNPs without a contract can continue to operate through 2010 but cannot expand their service areas. The contracts must include the SNP's responsibilities for providing or arranging for Medicaid services (including long term care services), the eligibility categories covered, Medicaid benefits covered under the SNP, cost sharing protections under the SNP, identification and sharing of information on Medicaid provider participation, eligibility verification for Medicare and Medicaid, the service area, and the contract period.

Dual SNP Cost Sharing and Comprehensive Written Statement Prior to Enrollment – The regulation includes the MIPPA provision that plans may not impose cost sharing that exceeds Medicaid cost sharing and that the plans must provide written notices that allow beneficiaries to compare the SNP and Medicaid benefits and costs prior to enrollment. The preamble states that CMS will develop a model that SNPs can use with any description of benefits. CMS has already issued instructions advising plans that they can change their Summary of Benefits to include the Title XIX benefits.

CMS will issue a separate final notice that addresses related provisions included in the proposed rule. CMS is still reviewing comments on whether to extend the MIPPA requirement that Dual SNPs limit cost sharing for full benefit duals and QMBs to these beneficiaries in all MA plans.

Private Fee for Service Access to Providers and Elimination of Deeming for Most Plans – The regulations add the MIPPA provisions that require plans to meet the access requirements for coordinated care plans in 2010; for plans in the individual market that are not in a “network area” in 2011; and for all employer plans in 2011.

The regulation clarifies that the network area test includes coordinated care plans (HMOs, PSOs, local PPOs and regional PPOs with written contracts that meet access standards, but not SNPs), network MSA plans and cost plans. For 2011, CMS will inform PFFS plans of their network areas in the announcement of CY 2010 capitation rates published on the first Monday of April 2009. For 2011, the "network areas" will be based on January 1, 2009 enrollment data.

If a plan has a service area where some counties meet the network test and others do not, CMS will require the PFFS plan to create two plans. Plans in the non-network area can continue to "deem" providers. Plans in a network area may continue to treat providers without a contract as deemed providers.

PFFS Plan Variation in Payment Rates to Providers – The regulation includes the MIPPA provision that PFFS plans can vary payment on the provider specialty and location or other non-utilization factors including increased rates for higher use of preventive or screening services. The regulation clarifies that payment rates can be included in the terms and conditions if they apply to all providers and that plans must maintain a record of all provider specific payment rates they negotiate along with the final rates paid.

PFFS and MSA Quality Improvement Program – The regulation includes the MIPPA provision that PFFS and MSA plans must operate a quality improvement program and report data on health outcomes. CMS regulatory guidance clarifies that this includes: quality improvement projects on an annual basis, chronic care improvement programs and plan encouragement of its providers to participate in CMS and HHS quality improvement initiatives. The regulation clarifies that reporting for 2011 applies to contracted providers and for 2010, plans must report quality data for all providers based on claims data (including contract, deemed and non-contract providers)

Phase Out of the Indirect Medical Education costs from MA Capitation Rates – The regulation includes the MIPPA provision.

Electronic Prescribing – The regulation includes the MIPPA provision that allows the use of part D drug claims (PDE data) to implement the electronic prescribing provisions.

Use of Part D Data – The regulation includes the MIPPA provision that Part D data can be used for Congressional oversight and analysis.

Part D Prompt Payment of Claims – The regulation includes the MIPPA provision that Part D plans pay claims promptly and pay long term care facilities timely and include this provision in contracts with long term care facilities. The preamble states that the regulation makes no distinction between a pharmacy and its agent for purposes of the prompt payment provision. The preamble notes that the long term care claims payment does not eliminate the requirement that Part D sponsors provide a new timely claims filing period for dual eligible beneficiaries during a period of retroactive part D enrollment.

Update of the Prescription Drug Pricing Standard - The regulation includes the MIPPA provision and clarifies that the Part D plan sponsor contracts with pharmacies, providers, first tier, downstream and related entities must include provisions for regular drug pricing updates. Part D plan sponsors must assure that fee schedules tied to the drug prices are updated timely and must document the source used for making pricing updates.

Low Income Subsidy (LIS) – The regulation precludes preclude late enrollment penalties and adds new definitions to implement the MIPPA changes to the income and resources test to qualify for low income subsidies. The provision adopts the methodology used by the Supplemental Security Income (SSI) program to determine financial eligibility.

Marketing – Nominal Gifts – The preamble clarifies that the nominal value gift must be available to all potential enrollees without regard to whether they enroll and that the nominal value of \$15 will be updated to account for inflation and other factors.

Marketing – Scope of Appointments – The regulation clarifies that beneficiary requests for appointments must be documented in writing agreeing to the products that will be discussed (signed by the beneficiary and not the sales representative) or recorded.

An appointment in response to a business reply card may only discuss the products included in the advertisement. The regulation retains the 48 hour cooling off period to discuss products not initially requested. Guidance clarifies that plan materials related to other products may be left during the initial appointment, provided enrollment applications are not included.

Marketing - Co-Branding – The guidance clarifies that MA organizations may include the provider names and/or logos selected by the member on the member ID cards and that Part D plans can display the names and logos of co-branded network providers on member ID cards.. Other MA and Part D plan marketing materials must clearly indicate that other providers are available in the network.

Marketing – Required Use of Plan Type - The regulations provide that the plan type should be included at the end of the plan name.

Marketing – State Reporting - The regulation includes a requirement that plans report the termination of an agent or broker and the reasons to the state if required under state law.

Marketing – Agent/Broker Compensation – The rule adopts a totally different compensation requirement than the requirement in the proposed rule. If plans (or other entities on behalf of the plan) compensate either employed or contracted agents or brokers, the compensation system must include a six year cycle where the first year may not exceed 200 percent of the aggregate in each of the five year renewal commissions.

The preamble clarifies that the first year is compared to any one of the five years (not the total of the five years). If the beneficiary switches to a “like” plan during the six year period, the compensation cannot exceed the renewal rate of the replacement plan. Replacements for a different type of plan can generate a new compensation. Compensation can be paid up front or monthly.

Compensation includes pecuniary and non-pecuniary remuneration including commissions, bonuses, prizes, gifts and finder's fees. Salaries unrelated to sales volume, sales expenses and payment of appointment fees are excluded. CMS will develop a tracking system to assist plans with payment of renewal fees when the beneficiary changes plans. No compensation can be earned if an enrollee leaves during the first three months and compensation is pro-rated for the months of actual membership. The compensation method for new and renewals must be in place by October 1 each year and cannot be modified.

Marketing – Agent/Broker Training and Testing – The regulation includes a requirement that agents and brokers be trained and tested annually on the products they intend to sell. The regulatory guidance clarifies that a passing score is 85 percent (previous guidance said 80 percent).

Marketing – Cooperation with a State Investigation – The regulation requires that plans comply with requests about the performance of an agent or broker as part of a state investigation.

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