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MEMORANDUM

Date: June 1, 2007

To: All Part D Plan Sponsors

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Subject: Convenient Access to LTC Pharmacies

Recently, CMS has been made aware that Part D sponsors may not have been provided with addresses that would help them: (1) confirm that a beneficiary is institutionalized, and (2) identify the particular long-term care (LTC) facility in the sponsor's service area in which those enrollees reside. We have also heard of difficulties associated with contracting efforts between Part D sponsors and State-operated pharmacies serving beneficiaries in institutions for mental disease (IMDs) and intermediate care facilities for the mentally retarded (ICFs-MR) designated by States as institutions. This memorandum provides guidance to Part D sponsors on both these issues.

1. Identifying the Locations of Institutionalized Enrollees

Access by a Part D sponsor to the addresses of its enrollees residing in LTC facilities promotes the efficient administration of its Part D plan and the sponsors' compliance with various requirements under Part D. Currently, CMS systems do not provide sponsors with address information that would allow sponsors to link an enrollee to a particular institution. We are currently working on a change to our systems that would ensure that Part D sponsors receive address information for their enrollees who are identified in our systems as residing in an institution. In the interim, however, we expect that sponsors will obtain address information from network pharmacies that serve enrollees in a sponsor's plan(s) within the scope of their current contacts. For the reasons discussed in Attachment 1, CMS believes the pharmacies' disclosure of LTC enrollees' addresses is permissible under the HIPAA Privacy Rule.

2. Contracting with State-Run Pharmacies

We are aware that there are special issues associated with the operations of State-owned or in-house LTC pharmacies that serve Part D enrollees residing in facilities (e.g., IMDs and ICFs/MR) recognized by States as institutions and that have as inpatients any institutionalized individuals (any full benefit dual eligible for whom payment is made under Medicaid throughout

a month, as provided in section 1902(q)(1)(B) of the Social Security Act). In section 50.5.1 of Chapter 5 of the *Prescription Drug Benefit Manual*, we have instructed sponsors to continue their contracting activity as they identify LTC facilities and LTC pharmacies, and as they examine their auto-enrollment assignments and incoming enrollments. As stated in section 50.5.4 of Chapter 5 of the *Prescription Drug Benefit Manual*, sponsors are not compliant with our LTC convenient access standard if they do not provide access to covered Part D drugs via a LTC pharmacy in their network for all of their enrollees who reside in LTC facilities. Thus, to the extent that State-owned and operated LTC pharmacies are involved, Part D sponsors should be prepared to readily negotiate with States to address contracting issues.

Several States have raised concerns that some sponsors are not acting in good faith to finalize contracts with State-owned and operated LTC pharmacies for both 2006 and 2007. Further, such complaints specify that sponsors are using the March 31, 2007 coverage year deadline for claims submission to avoid contracting for 2006 and, thus, paying claims for enrollees residing in some IMDs and ICFs/MRs. We clarify that to the extent a State attempted to contract with a sponsor throughout 2006 (and can document those efforts) on its State-run pharmacies' behalf, sponsors are still expected to continue to process claims for any of their enrollees residing in LTC facilities and to whom they were required to provide convenient access to a network LTC pharmacy in 2006.

We also clarify that if a State can establish a clear fact pattern that demonstrates that it attempted to contract with a sponsor throughout 2006, that the sponsor did not act in good faith, and that this is the reason the State was unable to secure contracts for its State-run LTC pharmacies, CMS will intervene to undertake any appropriate enforcement actions against the sponsor.

If you have any questions regarding convenient access to LTC pharmacies, please contact Vanessa Duran at Vanessa.Duran@cms.hhs.gov or 410-786-8697. We appreciate your continued support in meeting the needs of Medicare beneficiaries. Without your help, the Medicare prescription drug benefit would not be a success.

Attachment 1: HIPAA Permitted Disclosures of Beneficiary Address Information

Both LTC pharmacies and Part D plans are considered covered entities under the HIPAA Privacy Rule. As a covered entity, it is permissible for a LTC pharmacy to disclose protected health information, including beneficiaries' addresses consistent with the HIPAA Privacy Rule. In accordance with 45 CFR 164.506(c)(4)(i), a covered entity may disclose an individual's protected health information to another covered entity for the health care operations activities of the entity that receives the information, if: (1) each entity has a relationship with the individual, (2) the protected health information pertains to that relationship, and (3) the purpose of the disclosure is a purpose listed under paragraphs (1) or (2) of the definition of "health care operations" under 45 CFR 164.501. CMS believes the first requirement is satisfied when the beneficiary both obtains his or her prescriptions from the pharmacy disclosing the protected health information and is enrolled in the Part D plan receiving the information. The second requirement is satisfied because the individual's address is relevant to the Part D plan's ability to provide prescription drug benefits to the individual. With respect to the third requirement, purposes listed under paragraphs (1) and (2) of the definition of "health care operations" include: (1) population-based activities relating to improving health or reducing health care costs; and (2) evaluating provider performance. In CMS's view, the exchange of LTC enrollees' addresses falls under one of these two purposes when the Part D plan requests this information from a LTC pharmacy for the following purposes:

- **Ensuring a high-quality, cost-effective benefit.** Acquiring the addresses of its LTC enrollees may further a Part D plan's objective of providing a high-quality, cost-effective drug benefit to its LTC enrollees. Toward this end, a Part D plan will compare the competing LTC pharmacies available to serve its LTC enrollees, and focus its contracting efforts on those pharmacies providing the highest quality pharmacy services at the lowest cost. In order to identify those pharmacies available to serve its LTC enrollees, the Part D plan must know where those enrollees reside. Consequently, CMS believes the disclosure of LTC enrollees' addresses to the Part D plan by LTC pharmacies promotes the plan's population-based activities relating to improving health and reducing health care costs, and thus is a permissible disclosure under the HIPAA Privacy Rule.
- **Evaluating network pharmacies' performance.** Acquiring the addresses of its LTC enrollees may promote a Part D plan's ability to evaluate the performance of its network LTC pharmacies, specifically whether they are complying with the terms and conditions of their contract with the plan and the plan's LTC policies. For example, plans are required to have in place certain minimum transition process requirements, as provided in [section 30.4](#) of Chapter 6 of the *Prescription Drug Benefit Manual*. These transition requirements vary for institutionalized versus non-institutionalized beneficiaries (e.g., only enrollees residing in LTC facilities are entitled to 31-day temporary fills of non-formulary drugs, with multiple refills as necessary, during their transition period). In order to evaluate whether network pharmacies are adjudicating claims consistent with the appropriate transition requirements for institutionalized and non-institutionalized enrollees, it is necessary for the plan to know whether those enrollees reside in the community (including in a non-LTC facility) or in a LTC facility. Acquiring the addresses of enrollees will help the plan identify those

individuals who reside in long-term facilities and those who do not. Similarly, to the extent that a plan requires its network pharmacies to perform medication therapy management (MTM) activities for institutionalized beneficiaries but not for non-institutionalized beneficiaries, plans will be unable to fully evaluate their network pharmacies' performance vis-à-vis contractual agreements related to MTM activities if they cannot identify an enrollee as institutionalized. Finally, to the extent that a plan negotiates different dispensing fees with a network pharmacy for institutionalized versus non-institutionalized enrollees, that plan must be able to identify its institutionalized beneficiaries in order to assess whether a network pharmacy is adjudicating claims using the correct contractual negotiated price.

- **Sufficiency of Pharmacy Networks.** Evaluating the adequacy of sponsors' pharmacy networks is essential to building and maintaining a network that provides enrollees with convenient access to network pharmacies. Without knowledge of where enrollees reside, it would be difficult for a sponsor to ensure its compliance with the various pharmacy access requirements detailed in section 50 of Chapter 5 of the *Prescription Drug Benefit Manual*. This includes the convenient access requirements for retail and LTC pharmacies, as well as the adequate access requirement for home infusion pharmacies. Consequently, CMS believes the disclosure of LTC enrollees' addresses to the Part D plan by LTC pharmacies promotes the plan's population-based activities relating to improving health through improved network access, and thus is a permissible disclosure under the HIPAA Privacy Rule.

Additionally, the HIPAA Privacy Rule permits a covered entity, such as a LTC pharmacy, to disclose PHI to another covered entity for that covered entity's payment purposes. 45 CFR 164.506(c)(3). CMS believes the exchange of LTC enrollees' addresses falls under this provision when the Part D plan requests this information from a LTC pharmacy for the following purposes:

- **Correct Application of Cost-Sharing.** A Part D enrollee who is both a full-benefit dual eligible and resides in a LTC facility, as defined in section 10.2 of Chapter 5 of the *Prescription Drug Benefit Manual*, is eligible for no copays. In order to ensure the correct application of the institutionalized copays (\$0) for these low income subsidy eligible individuals, Part D plans need to identify who among their enrollees are institutionalized dual eligible individuals. Knowledge of an enrollee's residence in a LTC facility would assist plans in identifying these individuals.
- **Ensuring Uniformity of Benefits.** Sponsors need to know whether their enrollees reside in LTC facilities rather than in the community (including assisted living facilities and other forms of congregate residential setting that do not meet the definition of a "LTC facility") in order to ensure that they are providing a uniform benefit to all enrollees residing in LTC facilities, and a uniform benefit to enrollees residing in the community. For example, as discussed in section 50.5.3 of Chapter 5 of the *Prescription Drug Benefit Manual*, Part D sponsors may extend the transition period for LTC enrollees beyond 90 days, or may waive prior authorization or other utilization management edits for LTC enrollees, but not for non-LTC enrollees. Enrollee addresses will assist a sponsor in identifying its LTC enrollees so that it may ensure that plan benefits available to LTC enrollees are applied uniformly across

this population and are not extended to non-LTC enrollees. This falls within the definition of “payment” for purposes of the HIPAA Privacy Rule, since “payment” includes “activities undertaken by (i) a health plan ... to determine or fulfill its responsibility for coverage and provision of benefits under the health plan.” 45 CFR 164.501.

All of the above disclosures are subject to the HIPAA Privacy Rule’s minimum necessary standard. Accordingly, the LTC pharmacy must “make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.” 45 CFR 164.502(b)(1). The LTC pharmacy may rely on the plan sponsor’s request as requesting only the minimum necessary information, if the plan sponsor is a covered entity and such reliance is reasonable under the circumstances. 45 CFR 164.514(d)(3)(iii).