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Date: September 20, 2007

To: All Part D Plan Sponsors

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

Subject: Sponsor Activities Performed Outside of the United States (Offshore Subcontracting) Questions & Answers

CMS received several questions regarding the July 23, 2007 memo entitled *Sponsor Activities Performed Outside of the United States (Offshore Subcontracting)*. The questions and answers (Q&As) below address the issues raised by sponsors. These Q&As were originally discussed during the August 22, 2007 User Group Call. To clear up any confusion between the 2008 Call Letter and the July 23, 2007 memo, at this time CMS is requesting that Medicare Advantage (MA) organizations and Prescription Drug Plan (PDP) sponsors submit the Offshore Subcontractor Information and Attestation included in the July memo in order to comply with CMS' Medicare Part C and Part D guidelines. As a result of additional analysis conducted since the release of the Call Letter, CMS determined it will not evaluate or issue written approval of organizations' offshore subcontracting arrangements, as indicated in the Call Letter.

Q1. The July 23, 2007 memo indicated that MA organizations and PDP sponsors should take appropriate steps to address the risks of offshore subcontracting. Are there any documents that cover the appropriate steps?

A1. CMS is not endorsing any particular documents on this topic; however, to familiarize sponsors with the risks involved in offshore subcontracting, the Government Accountability Office's (GAO) Report entitled *Privacy: Domestic and Offshore Outsourcing of Personal Information in Medicare, Medicaid, and TRICARE* is a helpful resource. You may download the report by visiting the GAO's website at www.gao.gov and entering GAO-06-676 in the search box.

Q2. What are the definitions of "offshore" and "subcontractor" as used throughout the July 23, 2007 memo?

A2. First, CMS considers MA organizations and PDP sponsors to be "contractors" with respect to CMS for the purposes of delivering Medicare Part C and Part D benefits. The term "subcontractor" refers to any organization that a sponsor contracts with to fulfill or help fulfill requirements in their Part C and/or Part D contracts. Subcontractors include all first tier, downstream, and/or related entities.

The term “offshore” refers to any country that is not one of the fifty United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of “offshore” include Mexico, Canada, India, Germany, and Japan. Subcontractors that are considered offshore can be either American-owned companies with certain portions of their operations performed outside of the United States or foreign-owned companies with their operations performed outside of the United States. Offshore subcontractors provide services that are performed by workers located in offshore countries, regardless of whether the workers are employees of American or foreign companies.

Q3. Are the attestations required for all offshore work?

A3. For the offshore subcontract attestation, CMS is interested in receiving attestations pertaining to entities that sponsors contract with to receive, process, transfer, handle, store, or access beneficiary protected health information (PHI) in oral, written, or electronic form. Examples of PHI include beneficiary name, birth date, address, social security number, health insurance claim number, patient identifiers, medical diagnosis, medical history, treatment records, type of provider visited, use of health care services, payment information, evidence of insurance coverage, or any information that could reasonably lead to the identification of a beneficiary. For example, if a PDP sponsor contracts with and provides beneficiary PHI to a company in the U.S. that further contracts with and provides that beneficiary PHI to an offshore company in Mexico, then the PDP should submit an offshore subcontract attestation for the Mexican company because it received beneficiary PHI.

Q4. What is the definition of “Medicare-related work” as used in the July 23, 2007 HPMS memo?

A4. CMS interprets the term “Medicare-related work” broadly. Medicare-related work encompasses what offshore subcontractors do when they receive, process, transfer, handle, store, or access beneficiary PHI while helping sponsors fulfill their Medicare Part C and Part D contract requirements. For example, the term “Medicare-related work” includes offshore subcontractors that receive radiological images for reading, because beneficiary PHI is included with the radiological image and the diagnosis is transmitted back to the U.S. More examples of Medicare-related work include claims processing, claims data entry services, scanning paper claims to create electronic records, receipt of beneficiary calls, and any situation where the offshore subcontractor may have access to beneficiary PHI.

Q5. What if an MA organization or PDP sponsor does not engage in offshore subcontracts? Should it submit an offshore subcontract attestation?

A5. No. If an MA organization or PDP sponsor does not engage in offshore subcontracting that involves receiving, processing, transferring, handling, storing, or accessing PHI, then the sponsor does not need to submit an attestation to CMS.

Q6. How many MA organizations or PDP sponsors can be represented in a single offshore subcontract attestation?

A6. All sponsor contract IDs (e.g., H1234 or S1234) held by a single parent organization (as indicated in HPMS under Contract Management > Contract Reports > General Information Report) may be represented in the same attestation for a single offshore subcontractor. MA organizations and PDP sponsors not affiliated with the same parent organization cannot be included in the same attestation. If a sponsor chooses to submit one attestation for all contract IDs held by a single parent organization for a single offshore subcontractor, in Section A, Part I.1 of the offshore subcontract attestation, please list the parent organization name in addition to the legal entity name of the sponsors (as indicated in HPMS under the Basic Contract Data tab).

Q7. How often does CMS expect MA organizations and PDP sponsors to submit offshore subcontract attestations?

A7. CMS requests sponsors to submit offshore subcontract attestations whenever sponsors (a) enter into a contract with an offshore subcontractor for the first time; or (b) change the functions that a current offshore subcontractor performs. For example, if on November 1, 2008 an MA organization enters into an offshore subcontract for the first time to provide claims processing services, CMS expects the MA organization to submit an attestation on or by December 2, 2008, which is in accordance with the timeline provided in the July 23, 2007 memo. Also for example, if on April 15, 2008 a PDP changes the functions that a current offshore subcontractor performs by eliminating the offshore subcontractor's responsibility to scan claims but continues the offshore subcontractor's responsibility to provide call center services, CMS expects the PDP will submit an attestation with a modified listing indicating the changed functions in Section A., Part II. 2 on or by September 15, 2008.

Q8. What are CMS' expectations of the type of auditing MA organizations and PDP sponsors should perform?

A8. Sponsors are responsible for ensuring that offshore subcontractors abide by all applicable Medicare Part C, Part D, and HIPAA requirements. Sponsors have the discretion to determine the audit criteria that are important for continuing a relationship with an offshore subcontractor. CMS expects sponsors to adopt audit criteria substantial enough to ensure the appropriate protection of PHI.

Q9. Should the audit be completed on-site or through a desk-review?

A9. CMS suggests, but does not require, an on-site audit of offshore subcontractors. The purpose of an on-site audit is, in part, to observe whether beneficiary PHI is handled appropriately on a day-to-day basis. MA organizations and PDP sponsors may hire third-party audit organizations to conduct audits.