DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

CENTER FOR MEDICARE

DATE: May 21, 2013

TO: All Prescription Drug Plan and Medicare Advantage-Prescription Drug Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

SUBJECT: Clarification of Chapter 5 of the Prescription Drug Manual, Section 90.2.4. -- Controlled Substances

The purpose of this memo is to clarify CMS's guidance in Section 90.2.4 – Controlled Substances in Chapter 5 of the Medicare Prescription Drug Manual. We are clarifying that when a prescriber has an individual DEA number, we expect Part D sponsors to confirm that the controlled substance prescribed is consistent with that prescriber's DEA Schedule registration. This policy applies to all prescribers, including residents in hospitals. Since our guidance was limited to individual identifiers, if there is no individual prescriber DEA number to check, we do not require any further action by the sponsor.

Section 90.2.4 provides:

> [S]ponsors are required to confirm the validity of DEA numbers on Schedule II-V drug claims or map NPIs on these claims to the prescriber's DEA numbers. In addition, sponsors will be required to confirm that the controlled substance prescribed is consistent with the prescriber's DEA Schedule registration. As noted in section 90.2 of this manual, sources of state and federal data on providers are available to support sponsor efforts in this regard in addition to prescriber identifier validation services from commercial vendors. Sponsors should understand that this requirement supports (and does not supersede or alter) existing pharmacy obligations relative to DEA registrants under the Controlled Substances Act and DEA rules.

Thus, Medicare Part D sponsors must confirm that controlled substances are consistent with the prescriber's Drug Enforcement Administration (DEA) Schedule registration. However, we have received reports that sponsors are rejecting claims for controlled substances when a prescriber is prescribing under a hospital's or institution's DEA registration, and the prescriber does not have an individual DEA registration. We are concerned that such rejections may interfere with beneficiary access to needed medications, and result from a misinterpretation of our guidance. We do not believe that sponsors have reasonable access to the information necessary to research the relationship of individual prescribers to group DEA numbers, and have not required this in our guidance.

As noted in Section 90.2.4 of Chapter 5, sponsors should understand that our policy supports (and does not supersede or alter) existing pharmacy obligations relative to DEA registrants under the Controlled Substances Act and DEA rules.

Any questions on this clarification may be directed to PARTDPOLICY@cms.hhs.gov.