The Centers for Medicare & Medicaid (CMS) has requested that the Transaction Facilitator remind pharmacists who utilize Eligibility Inquiries (E1s) of the following guidance.

The Part D transaction facilitation process, which includes the processing of all Medicare E1 transactions, is funded through the Part D coordination of benefits (COB) user fee. In accordance with the Social Security Act section 1860-D 24(a)(3), this user fee is to support the transmittal of information necessary for the purpose of accurate Part D benefit coordination. Federal regulations at 42 CFR 423.464 require Part D sponsors to coordinate with other entities providing prescription drug coverage in order to determine whether costs for Part D eligible individuals are being reimbursed by another entity and whether such costs may be treated as incurred costs and, therefore, are TrOOP-eligible.

Coordination of benefits includes confirming coverage under Medicare D in preparation for filling a prescription initiated by a prescriber. It is CMS' interest to ensure that eligibility transactions submitted through an E1, a 270/271 or via HETS or to health plans, and the data provided in the responses, are accessed and used appropriately. That is, the transactions are requested by a pharmacy for Medicare purposes and the data are used exclusively to support coordination of benefits for Medicare beneficiaries. Pharmacies should note the following:

- Eligibility responses provide protected health information (PHI) for Medicare beneficiaries. The HIPAA Privacy Rule establishes controls over how PHI can be used and disclosed. With few exceptions, any communication that meets the definition of marketing is not permitted, unless the covered entity obtains an individual's authorization. (See https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/marketing/index.html).

- Relying on eligibilities transactions to facilitate provision of unnecessary services is strictly prohibited. In general the Medicare program only pays for items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." See 42 U.S.C. § 1395y(a)(1)(A). Federal law and regulations require that any health care provider who furnishes health care services that may be reimbursed under Medicare, Medicaid, or TRICARE must ensure that, to the extent of his or her authority, those services are provided "only when, and to the extent, medically necessary." (See 42 U.S.C. § 1320c-5(a); 42 C.F.R. § 1004.10)

- Consistent with HHS Rules of Behavior for the Use of HHS Information and IT Resources Policy, pharmacies may not allow third party companies, including business associates, to use their E1 access. (See Appendix A: Rules of Behavior for General Users at https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-rules-of-behavior-for-the-use-of-hhs-information-and-it-resources-policy.html#3.1)

- Using the E1 to confirm coverage under Medicare D for reasons other than in order to fill a prescription initiated by a legally authorized clinician is not permitted.

- Pharmacies must ensure that beneficiary information such as that gained through Eligibility transactions comply with all existing data use agreements and existing laws.

If you have any questions about whether use of E1 data is in violation of these policies, please contact PartD_COB@cms.hhs.gov.