often identify patterns of potential inappropriate prescribing and drug utilization based upon drug claim history.

Response: Based upon these comments as well as similar information provided in the Booz-Allen-Hamilton report, we agree that concurrent and retrospective DUR must be components of the quality assurance systems and measures to be implemented by Part D plans. Accordingly, we have specified requirements for concurrent and retrospective DUR systems, policies, and procedures at § 423.153(c)(2) and § 423.153(c)(3), respectively.

In the proposed rule, we stated that elements we viewed as desirable for quality assurance systems were: (1) electronic prescribing; (2) clinical decision support systems; (3) educational interventions; (4) bar codes; (5) adverse event reporting systems; and, (6) provider and patient education.

While we did not expect Part D plans to adopt all of these elements, we stated that we expected substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market being created by the new Part D benefit.

We invited comments on which, if any, elements of a quality assurance system should be contained in our program requirements. We were particularly interested in best practices in quality assurance, costs and benefits associated with each element, the challenges involved in implementing quality assurance measures and systems, types of data useful for reducing medication errors, associated costs and challenges with collecting this data, and how these data could best be communicated to providers and beneficiaries to improve medication use.

We noted that the MMA does not define or explain the term ''medication error.'' Nevertheless, we stated that we believe a common definition was important. Therefore, we cited the following definition as one that we might use initially in interpretive guidance, which was previously adopted by the FDA in its proposed rule requiring bar codes on human drug products:

''Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.'' (See 68 FR 12500 (March 14, 2003)).

We indicated that in the future we may require quality measures that include error reports and stated that we could use this information to evaluate plans. In addition, we indicated that we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we invited specific comments on how we could evaluate Part D plans based on the types of quality assurance measures and systems they have in place, on this proposed definition of ''medication error'', on how error rates can be used to compare and evaluate plans, and on how such information could best be provided to beneficiaries to assist them in making their choices among plans.

Comment: A number of commenters recommended we include all elements discussed in the proposed rule including decision support, electronic prescribing, bar codes, adverse event reports, and provider and patient education. Most of them recommended that we require adverse event and medication error tracking systems. However, many commenters recommended that these tracking systems be used internally and that reports not be sent to CMS or made public. These commenters argued that there is too much inconsistency in the definitions used in the field and that an external reporting requirement would actually be counter productive for quality improvement. While several commenters generally thought our proposed definition for ''medication error'' was accurate, these same commenters stated that such a definition would need to be narrowed to prove useful for consistent reporting among the plans.

Response: As to all the elements that we listed in the preamble, we agree with the many industry organizations that there are no well accepted industry standards to make these mandatory requirements. The Booz-Allen-Hamilton report[4] supports this finding. We continue to believe that these are desirable goals and have found that many organizations are already using them. We expect that electronic prescribing will greatly increase the availability of clinical decision support. We intend to work with various stakeholders to further develop these and other quality assurance systems enhancements.

We agree with commenters that there are inconsistencies associated with the reporting of adverse events and medication errors. Moreover, we are not convinced, based upon many of the comments received, that an external reporting requirement for medication errors, even if we provided a more specific and narrow definition of ''medication error'', will lead to improved quality of care. Therefore, instead of requiring plans to report medication errors to us, we require plans to implement internal medication error identification and reduction systems, and we have added this requirement at § 423.153(c)(4). We are also requiring plans to provide us with information concerning their quality assurance measures and systems, in accordance with guidelines published by us. In addition, we encourage plans to utilize the FDA Medwatch form for reporting adverse events, as well as educating prescribers and pharmacy providers about its availability. Finally, although we will not require external medication error reporting at this time, we maintain that our proposed definition of ''medication error'' can still serve as appropriate guidance for internal medication error identification and reduction systems.

c. Medication Therapy Management Programs (MTMPs)

Proposed § 423.153(d) required Part D sponsors to establish an MTMP described in section 1860D–4(c)(2) of the Act that is designed to optimize therapeutic outcomes for targeted beneficiaries by improving medication use and reducing adverse drug events, including adverse drug interactions, that may be furnished by a pharmacist, and that may distinguish between services in ambulatory and institutional settings. We stated that MTMPs may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding—through beneficiary education counseling, and other means that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, compliance programs, and other appropriate means).
- Detection of adverse drug events and patterns of over-use and under-use of prescription drugs.

We proposed that in order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision MTMPs potentially spanning a range of services, from simple to complex. In addition to those mentioned in the statute, services could include, but may not be limited to, performing patient health status

[4] Ibid.