Comment: Several commenters suggested that we list all regulations and manual chapters applicable to each element.
Response: CMS has adopted this recommendation.

Comment: Several commenters noted the duplication of element numbers used throughout the Universal Audit Guide and recommended the duplication be corrected by assigning unique element numbers.
Response: CMS has adopted this recommendation.

Comment: Several commenters recommended formatting changes throughout the Universal Audit Guide such as inserting page numbers and correcting various typos.
Response: CMS has adopted these recommendations.

Comment: Several commenters requested that we specify which elements are applicable to specific types of Medicare Part C and Part D plans such as RPPO, SNP, PFFS, Cost plans.
Response: We have identified whether elements are applicable to Part C and/or Part D. We are concerned that plans may be using the Universal Audit Guide to dictate their internal operating procedures. To be clear, the Universal Audit Guide may not represent all requirements that plans are responsible to comply with and therefore should never be used to guide a plan's internal operations. Plans should be referring to statute, regulations, and manuals for the requirements that they are required to comply with and should not be using an audit guide to steer their internal operations. Plans should not be using the Universal Audit Guide as a basis to determine plan requirements.

Comment: A couple of commenters indicated the verbiage pertaining to Chapter 1 Element ER14: *Working Aged Survey* should be amended based on the 2010 CMS Call Letter.
Response: CMS agrees that the language did not reflect updates established in the 2010 CMS Call Letter and have updated the guide accordingly.

Comment: One commenter expressed their concern that auditors may use different standards when reviewing Chapter 10 Element EP01: *Electronic Prescribing*. They requested that we provide clarification in this element further describing the element and its requirements.
Response: The purpose of the audit guide is not to detail all program requirements. If a plan wants more information regarding a specific element listed and wants CMS' full guidance and instructions around the requirements for that element, please refer to the regulatory and manual citations listed for the element in question. Plans should not be using the Universal Audit Guide as a basis to determine plan requirements.

Comment: Several commenters requested that we publish methods of evaluations and worksheets to aide plans in preparing for audit.
Response: We consider methods of evaluations and worksheets internal audit tools and will not be releasing these internal documents. The purpose of publishing the audit guide is to allow plans' an opportunity to determine the level of effort required in this information collection effort. Worksheets and MOEs are used internally to evaluate information after it has been collected; they are never used to actually collect information and are therefore not pertinent to establishing a plan's level of effort during an audit. CMS has provided the tool that is used for

data collection that will be sent to plans during audits. CMS expects plans to develop and conduct their own internal monitoring efforts to ensure all CMS requirements are met.

Comment: A couple of commenters requested that we define terms in the Universal Audit Guide such as sample element, on-site element and ongoing element.
Response: These terms were accidentally included in the Universal Audit Guide and are internal references used by us to identify at what point an element is evaluated. These terms have been removed to eliminate any confusion as they are not relevant to materials a sponsor must provide for audit.

Comment: One commenter suggested that the burden estimates projected by CMS appeared low and requested they be revised to adjust for various factors including non-dedicated programming staff, customized data and information collection required during audit.
Response: CMS was able to reduce burden calculations based on several changes which have occurred. These changes include conducting targeted, data-driven and risk-based audits and allowing requested audit information to be burned to a CD thereby eliminating the need for a plan to print, copy or ship large quantities of paper which greatly reduces the hours required to respond to these requirements. Finally, without specific information we cannot consider changing our burden estimate.

Comment: A couple of commenters requested a "redlined" version of the Universal Audit Guide and/or a list of new elements added to the guide.
Response: The Universal Audit Guide is a combination of the following prior audit guides; MA, MAPD, PDP, PFFS, RPPO, SNP and Cost plans. Therefore, there are no new elements nor is there an available "redlined" version.

Comment: One commenter suggested a crosswalk of the old audit guide to the Universal Audit Guide be provided to show the old audit element number and the new audit element number if changed.
Response: The Universal Audit Guide is a combination of the following prior audit guides; MA, MAPD, PDP, PFFS, RPPO, SNP and Cost plans. Therefore, there are no new elements. The regulatory and manual citations listed for each element should be sufficient information for plans who wish to know what audit guides such element previously appeared in. To the extent that an element was specific to a certain plan type, we have indicated this in the element.

Comment: One commenter recommended that Chapter 8 Element GV01: *Organization Determinatios and Reconsiderations Not Categorized as Grievances* and GV02: *Grievance Decision Notification (Timeliness)* include additional descriptions.
Response: For additional information on these and any other elements, please refer to the regulatory and manual citations listed for that element. Plans should not be using the Universal Audit Guide as a basis to determine plan requirements.

Comment: One commenter inquired if the Marketing Guide would continue to be a standalone guide for compliance or will it become integrated into the Universal Audit Guide.

Response: We evaluate marketing requirements as demonstrated in Chapter 4: *Marketing* in the Universal Audit Guide. The Medicare Marketing Guidelines is a separate tool used by sponsors to understand compliance with CMS requirements.

Comment: One commenter requested that elements be alphabetized for easier referencing.
Response: The Universal Audit Guide is currently organized by subject matter (e.g., Chapter 4: *Marketing* includes all the Marketing elements), which CMS believes is the most understandable format. Listing elements in alphabetical order would mix elements on different subjects and we believe that this would serve no additional referencing purpose.

Comment: One commenter asked for the anticipated effective date and publication date of the Universal Audit Guide.
Response: Guides are usually uploaded into HPMS at the beginning of the year, in this case 2010.

Comment: One commenter suggested that Chapter 15 Element CP01: *Compliance with Federal and State Standards* should have the statement "by the time a Part D contract with CMS is signed" removed as this is not currently required by law or CMS guidance.
Response: In accordance with Federal regulations at 42 CFR §423.504(b) and published CMS guidance, a Part D plan sponsor must establish a compliance plan no later than the pending contract signature date in order to contract as a Part D plan sponsor. CMS has updated element CP01 accordingly.

Comment: One commenter requested that we provide Medicare Part C Fraud, Waste and Abuse guidance relative to compliance plans.
Response: Medicare Part C Fraud, Waste and Abuse guidance can be found in Federal regulations at 42 CFR §422.503(b)(4)(vi) and the December 5, 2007 Final Rule at Federal Regulations Vol. 72, No. 233. Pages 68705-68707.

Comment: One commenter suggested that Chapter 15 Element CP08: *Comprehensive Fraud and Abuse Plan* be removed stating there were no Federal laws requiring this element.
Response: In accordance with Federal regulations at 42 CFR §422.503(b)(4)(vi) and §423.504(b)(4)(vi), a plan sponsor is required to have a compliance plan that must include measures to detect, correct, and prevent fraud, waste and abuse.

Comment: One commenter pointed out the duplicity between Chapter 1 Element numbers ER05: *Enrollment Acknowledgement* and ER20: *Enrollment Notice Requirement*, recommending that Element ER20 is satisfied by ER05.
Response: CMS has adopted this recommendation.

Comment: One commenter suggested that Chapter 4 Element MR08: *No Engagement in Activities Which Mislead, Confuse, or Misrepresent the Sponsoring Organization* lists references to the Medicare Marketing Guidelines twice, recommending the duplicative reference be removed.
Response: CMS reviewed this section and did not find any duplication.

Comment: One commenter requested clarification on Chapter 1 Element DN04: *Refund of Premium* specifically for the term "incorrectly collected."
Response: For additional information, please refer to the regulatory and manual citations listed for each element. Plans should not be using the Universal Audit Guide as a basis to determine plan requirements.

Comment: One commenter requested clarification on Chapter 8 Element CD05: *Decision to Accept or Deny a Request to Expedite a Coverage Determination* specifically for the term "complaint."
Response: For additional information, please refer to the regulatory and manual citations listed for each element. Plans should not be using the Universal Audit Guide as a basis to determine plan requirements.

Comment: One commenter asked that we clarify if plans were still accountable for Chapter 8 Elements OP10: *Detailed Explanation of Non-Coverage (Timeliness)* and OP11: *Detailed Explanation of Non-Coverage (Notice Content)* and to provide additional descriptions.
Response: These are current elements that CMS may review upon audit. For additional information on these and any other elements, please refer to the regulatory and manual citations listed for each element. Plans should not be using the Universal Audit Guide as a basis to determine plan requirements.

Comment: One commenter suggested that Chapter 13 Elements OC01 through OC07, OC201 & OC202 should be moved to Chapter 12 "Claims Processing and Payment" as they deal solely with claims.
Response: Elements OC01 through OC07, OC201 and OC202 currently fall under Chapter 8: *Organizational / Coverage Determinations, Appeals and Grievances* (as opposed to the stated Chapter 13). CMS believes the commenter was suggesting moving these elements to Chapter 17: *Claims Processing and Payment* (as opposed to the stated Chapter 12). The listed elements deal with coverage determinations, as opposed to claims processing, which is why we believe these elements more closely fit (and should remain) within Chapter 8.