Discussion of CY 2011 Data Validation Requirements
(As stated in CMS-1414-FC (74 FR 60316))

3. HOP QDRP Validation Requirements

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68776), we announced a voluntary test validation program, the results of which would not affect the CY 2010 payment update for any hospital. Due to resource constraints, we were not able to implement this test validation plan.

a. Data Validation Requirements for CY 2011

Validation, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66871), is intended to provide assurance of the accuracy of the hospital abstracted data. For the CY 2011 payment determination, in the CY 2010 OPPS/ASC proposed rule (74 FR 35402), we proposed to implement a validation program that will require hospitals to supply requested medical documentation to a CMS contractor for purposes of being validated. However, the results of the validation will not affect the CY 2011 payment update for any hospital. We believe that it is important for hospitals to have some experience and knowledge of the HOP QDRP validation process before payment determinations are made based upon validation results. We proposed to implement a validation program that will both limit burden upon hospitals, especially small hospitals, as well as provide feedback to all hospitals on validation performance.

Specifically, we proposed to select a random sample of 7,300 cases from all cases successfully submitted to the OPPS Clinical Warehouse by all participating hospitals for the relevant time period described below and validate those data. Based upon the quality data submitted for the CY 2009 payment update and our methodology for drawing the sample, we estimate that the sample will include up to 20 cases per participating hospital; the same number of cases sampled on an annual basis for validation under the RHQDAPU program. A sample size of 7,300 was chosen because it will enable us to detect a relative difference of 10 percent in the measured overall accuracy rate with a 95 percent (two-tailed) confidence interval and should provide sufficient data to conduct post-hoc stratified analyses that provide meaningful feedback. These figures are based upon a power analysis assuming a population measure mismatch rate of five percent with the outcomes being either a match or a mismatch between what the hospital submitted versus what was determined by validation. We intend to supply feedback on the validation results to all hospitals.

We proposed to request medical documentation from hospitals for April 1, 2009 through March 31, 2010 episodes of care, which will allow us to gather one full year of submitted data for validation purposes.

Once we have completed the random selection, a designated CMS contractor will use certified mail to request that each selected hospital send to the CMS contractor supporting medical record documentation that corresponds to each selected episode of care. Each hospital must submit this documentation to the designated CMS contractor within 45 calendar days of the date of the

request (as documented on the request letter). If the hospital fails to comply within 30 days of the initial medical documentation request, the designated CMS contractor will send a second certified letter to the hospital reminding the hospital that the requested documentation must be received within 45 calendar days following the date of the initial request. If the hospital still fails to comply, a "zero" score will be assigned to each data element for each selected case and the case will fail for all measures in the same topic (for example, OP-6 and OP-7 measures for a surgical care case).

Once the CMS contractor receives the requested medical documentation, the CMS contractor will independently reabstract the same quality measure data elements that the hospital previously abstracted and submitted and compare the two sets of data to determine whether they match. Specifically, the CMS contractor will conduct a measures level validation by calculating each measure within a submitted record using the independently reabstracted data and then comparing this to the measure reported by the hospital; a percent agreement will then be calculated.

As we stated above, the results of the validation will not affect a hospital's CY 2011 annual payment update because we want to give hospitals time to gain experience with the medical documentation requests and the validation process before these results are used in payment determinations. However, hospitals must supply the medical documentation for each requested case; failure to provide this documentation may result in a 2.0 percentage point reduction in a hospital's CY 2011 annual payment update.