

After carefully examining Section 1847A of the Social Security Act, as established in the MMA, CMS is conducting a review to ensure that separate payment is made for single source drugs and biologics as required by this section of the Act. In order to facilitate separate payment, it may be necessary to create unique HCPCS level II codes for certain products. As part of this effort, we will also review how we have operationalized the terms 'single source drug,' 'multiple source drug,' and 'biological product' in the context of payment under section 1847A to identify the potential need to make any changes to our assignment of National Drug Codes to billing codes for payment purposes. In the coming months, we will post additional information along with a preliminary list of drugs and biologics potentially affected.

So that we can implement any necessary changes during 2007, CMS will use its internal process for modifying the code set. While internally generated code requests are not part of the HCPCS public meeting process, CMS will consider any comments on potentially affected drugs and biologics and input to conventions for code descriptors and units of measure. Comments can be sent to [HCPCS@cms.hhs.gov](mailto:HCPCS@cms.hhs.gov).