



**News Flash** - An additional election period for the Competitive Acquisition Program (CAP) for Medicare Part B drugs will start on January 15 and run through February 15, 2008, to give physicians a chance to take advantage of new changes to the program that began on January 1, 2008. The CAP is a voluntary program that provides an alternative to ASP for physicians to obtain certain Part B drugs. More information about the CAP is available at [http://www.cms.hhs.gov/CompetitiveAcquisforBios/01\\_overview.asp](http://www.cms.hhs.gov/CompetitiveAcquisforBios/01_overview.asp) on the CMS website.

MLN Matters Number: MM5805

Related Change Request (CR) #: 5805

Related CR Release Date: January 18, 2008

Effective Date: January 1, 2008

Related CR Transmittal #: R1418CP

Implementation Date: No later than April 7, 2008

## New Healthcare Common Procedure Coding System (HCPCS) Modifiers when Billing for Patient Care in Clinical Research Studies

### Provider Types Affected

Physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), including Regional Home Health Intermediaries (RHHIs), Medicare Administrative Contractors (A/B MACs) and Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for services provided to Medicare beneficiaries in clinical research studies.

### What Providers Need to Know

This article is based on Change Request (CR) 5805. The Centers for Medicare & Medicaid Services (CMS) is discontinuing the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007, and creating two new modifiers that will be used solely to differentiate between routine and investigational clinical services.

These new modifiers will be included in the 2008 Annual HCPCS Update and are effective for dates of service on and after January 1, 2008:

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

**Q0** - Investigational clinical service provided in a clinical research study that is in an approved clinical research study. Q0 replaces QA and QR.

**Q1** - Routine clinical service provided in a clinical research study that is in an approved clinical research study. Q1 replaces QV.

Use these two new modifiers as follows:

Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.

Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent), clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers), and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).

Medicare contractors will not search their files to adjust affected claims processed prior to implementation of this change, but they will adjust such claims that you bring to their attention.

**Note: If a Category A or B investigational device is used on the clinical trial, providers should continue to include the Investigational Device Exemption (IDE) in item 23 of the CMS-1500 claim form or the electronic equivalent. Also, your Medicare contractor will validate the IDE# number when it appears on the claim with the Q0 modifier and if the IDE# does not meet validation criteria, the claim will be returned as unprocessable.**

## Additional Information

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If you have questions, please contact your Medicare A/B MAC, FI, DMERC, DME/MAC, RHHI or carrier at their toll-free number which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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You may see the official instruction (CR5805) issued to your Medicare A/B MAC, FI, DMERC, DME/MAC, RHHI or carrier by going to <http://www.cms.hhs.gov/Transmittals/downloads/R1418CP.pdf> on the CMS website.

**News Flash** - It's Not Too Late to Get the Flu Shot. We are in the midst of flu season and a flu vaccine is still the best way to prevent infection and the complications associated with the flu. But re-vaccination is necessary each year because flu viruses change each year. Please encourage your Medicare patients who haven't already done so to get their annual flu shot. – And don't forget to immunize yourself and your staff. Protect yourself, your patients, and your family and friends. Get Your Flu Shot – Not the Flu! Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. Health care professionals and their staff can learn more about Medicare's coverage of adult immunizations and related provider education resources, by reviewing Special Edition MLN Matters article SE0748 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0748.pdf> on the CMS website.

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