

Open Door Forums Special Announcement: Schedule Change *and* New Open Door Forum Announcement:

DATE: April 20, 2004

- **Special Listening Session on MMA Section 303(d):**
(Competitive Bidding for Part B Drug Distribution beginning in 2006)

TIME CHANGE:

Will now be condensed to only one hour in length, from 2:00PM to 3:00PM (EST).

The second hour, (from 3:00PM to 4:00PM) will be modified as follows:

ADDED FORUM Topic:

- A Special Open Door Forum will run from 3:00PM to 4:00PM to allow CMS to provide an interactive **Question and Answer period** related to **Manufacturer Submission of Average Sales Price data for Medicare Part B Drugs**. This is a follow-up to concerns raised after having a previous Open Door Forum Listening Session on March 2, 2004 and prior to having published the recent Interim Final Rule with comment period in the Federal Register on April 6, 2004.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) included several important provisions related to drug coverage and payment in the Medicare program.

One of the provisions establishes a new Average Sales Price (ASP) payment system beginning in 2005 for Medicare Part B covered outpatient drugs and biologicals not paid on a cost or prospective payment system basis, including drugs furnished incident to a physician's service, drugs furnished under the durable medical equipment (DME) benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs. Section 303 of the MMA requires manufacturers of these drugs and biologicals to submit quarterly ASP data to the Centers for Medicare and Medicaid Services (CMS) beginning April 30, 2004.

CMS recently published an Interim Final Regulation with Comment "Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals" and is interested in holding this Special Open Door Forum Session to answer questions related to the submission of ASP data by manufacturers and to allow interested parties to hear and be heard by other members of the healthcare industry.

If necessary, we will post additional information regarding this Special Listening Session on the following website: <http://www.cms.hhs.gov/providers/drugs/default.asp>.
Questions may be sent in advance to Sec303ASPdata@cms.hhs.gov.

Participation instructions:

There are 2 ways to participate in both of these Open Door Forum Sessions, by phone or in-person.

To participate in-person at the CMS Baltimore Site, an **RSVP is required**.

To register, please **RSVP** (by close of business **Thursday April 15, 2004**) via email to MMA303DDrugBID@cms.hhs.gov if you plan to attend. Please include the word "Registration" in the subject line of your message, send us your name along with the name of your organization, and contact information, and **indicate whether or not you plan to speak**. Please arrive no later than 1:30 PM. Photo identification is required at security points.

ADDRESS:

CMS Single Site Building

Auditorium

7500 Security Boulevard

Baltimore, MD 21244

Map & Directions: <http://cmsnet.cms.hhs.gov/hpages/ocsq/cmsdirections-north.htm>

To participate by phone:

Dial: 1-800-837-1935

- **Reference Conference ID: 6330178** if you plan to only dial in for the **first** hour (at 2:00PM) regarding *Competitive Bidding for Part B Drugs in 2006*
- Also use Conference ID **6330178** if you plan to attend **both sessions** for the full two-hour period. (There will be no need to hang up and re-dial in again.)
- **Reference Conference ID: 6655670** if you plan to **only** dial in for the 3:00PM **Question and Answer Session** on *Submission of Manufacturer ASP Data for Part B Drugs*.

Note: TTY Communications Relay Services are available for the Hearing Impaired. For TTY services dial 7-1-1 or 1-800-855-2880 and for Internet Relay services click here <http://www.consumer.att.com/relay/which/index.html> .

A Relay Communications Assistant will help.

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- **ENCORE Telephone Replay: 1-800-642-1687; Conf. ID# 6330178** for the **Special Listening Session on MMA Section 303(d)**: (Competitive Bidding for Part B Drug Distribution beginning in 2006)
- **ENCORE Telephone Replay: 1-800-642-1687; Conf. ID# 6655670** for the **Question and Answer Session** on *Submission of Manufacturer ASP Data for Part B Drugs*.

"Encore" is a recording of this call that can be accessed by dialing 1-800-642-1687 and entering the Conf. ID beginning 2 hours after the call has ended. The recording expires after 4 full days.

For Forum Schedule updates, Listserv registration and Frequently Asked Questions please visit our website at www.cms.hhs.gov/opendoor/

Thank you.