



## CENTER FOR MEDICARE

---

TO: All Part D Plan Sponsors

FROM: Tracey McCutcheon, MHSA, MBA  
Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Submission of a Health Information Technology for Economic and Clinical Health Act (HITECH) Business Associate Agreement with the Part D Transaction Facilitation Contractor

DATE: April 1, 2014

The purpose of this memo is to remind Part D sponsors of the need to execute and submit a revised Business Associate Agreement (BAA) with the Part D Transaction Facilitation Contractor, NDCHealth dba RelayHealth, to cover TrOOP and coordination of benefit (COB)-related functions. The requirement to execute a BAA with the Transaction Facilitator is addressed in our guidance in Section 50.13 of Chapter 14 of the Medicare Prescription Drug Benefit Manual. Because the Transaction Facilitation Contractor performs TrOOP and COB functions on behalf of the Part D sponsor when it receives data directly from the sponsor, each Part D sponsor must enter into a BAA with the Transaction Facilitation Contractor, consistent with the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164). A revised BAA is necessary to address recent changes to the HIPAA Privacy Rule.

The Office for Civil Rights (OCR) codified new HIPAA Privacy Rule requirements in an omnibus final rule that was published on January 25, 2013 (78 FR 5566), which addresses a number of HIPAA-related issues. Among other things, the omnibus regulation extended certain HIPAA requirements to business associates. The attached BAA is intended to reflect these changes.

The omnibus changes went into effect on September 23, 2013. However, provided that the governing agreements were not modified prior to that date, sponsors have been given until September 1, 2014 to execute revised BAAs. To ensure no lapse in services, plan sponsors should complete and sign the updated BAA as soon as possible. The BAA, an implementation form and instructions for the completion and submission of the documents are available on the Facilitator's website at <http://medifacd.relayhealth.com/fir/baa>.

Click on the icon labeled Transaction Facilitator BAA Agreement with Implementation Form (circled in red in the graphic attachment included with this memo).

As part of the forthcoming annual Readiness Checklist Assessment for 2015, we are

requiring sponsors to report if the executed BAA covers all contracts and, if appropriate, to specify which contracts are not covered and the projected date for executing a BAA to include these contracts. CMS will consider sponsors without an executed BAA in place by September 1, 2014 for existing plans and/or January 1, 2015 for new plans effective in 2015 out of compliance with Part D requirements related to COB and TrOOP balance tracking and transfer. Such sponsors may receive compliance notices from CMS and, in the event of continued non-compliance, may be subject to intermediate sanctions (e.g., suspension of marketing and enrollment activities) pursuant to 42 C.F.R. Part 423, Subpart O. We plan to include further details on this information collection effort in the annual Readiness Checklist Assessment instructions.

If you have any questions about accessing or submitting the documents referenced in this memo, please contact RelayHealth at [TBTBAA@RelayHealth.com](mailto:TBTBAA@RelayHealth.com).

# Attachment

The screenshot shows a web browser window displaying the RelayHealth Business Associate Agreement (BAA) page. The browser's address bar shows the URL: <http://medfacid.relayhealth.com/fo/baa>. The page header includes the RelayHealth logo and navigation links for E1, FIR, Nrx, Switches, and a Glossary. The main heading is "Business Associate Agreement (BAA)".

The page content is organized into a sidebar on the left and a main content area on the right. The sidebar contains the following links:

- Overview
- FIR Reports
- Setting up Points of Contact for a Contract ID
- Non Plan of Record
- Manual FIR Retrieger
- FIR History Request Form
- FAQ
- FIR Certification and Testing
- Business Associate Agreement (BAA)**

The main content area features a search bar, a "Contact Support" dropdown, and a section titled "RELAY DOCUMENTS". This section contains a list of documents:

- FIR PAYER SHEETS
  - FIR v1.2
- RELAY DOCUMENTS
  - Transaction Facilitator HITECH BAA Agreement with Implementation Form**
  - Implementation Form to Add Contract IDs to Existing BAA
  - Fax Cover Page for BAA

A red circle highlights the "Transaction Facilitator HITECH BAA Agreement with Implementation Form" link. Below the document list, there is a note: *All Part D Plans that currently have a non-HITECH version of the BAA, must have the new BAA signed and submitted to RelayHealth by September 1, 2014.*

The browser's taskbar at the bottom shows the system tray with the date and time: 11:03 AM 3/27/2014.