



Mitsubishi Tanabe Pharma America, Inc.
525 Washington Blvd. Ste 1100
Jersey City, NJ 07310

September 2, 2025

Notice Regarding Mitsubishi Tanabe Pharma America's 340B Contract Pharmacy Policy

Dear Covered Entity,

I am writing to inform you that Mitsubishi Tanabe Pharma America ("MTPA") is changing its approach to distributing products purchased at the 340B price. Effective October 1, 2025, MTPA is implementing a policy regarding contract pharmacies' eligibility to receive our specialty product Radicava ORS® (edaravone) purchased at the 340B price (our "Contract Pharmacy Policy"). Under our new policy, MTPA will no longer facilitate Radicava ORS "Bill To/Ship To" 340B contract pharmacy replenishment orders, other than pursuant to the exceptions listed below:

- MTPA will permit 340B covered entities to designate a single contract pharmacy location regardless of the covered entity's ability to dispense outpatient drugs to eligible patients at the 340B price through an in-house pharmacy, provided the designated contract pharmacy is part of Mitsubishi Tanabe Pharma's limited distribution network for Radicava ORS or is a specialty pharmacy under common ownership with the covered entity that is listed as a contract pharmacy in the Health Resources and Services Administration ("HRSA") OPAIS database.
- MTPA will also require the submission of claims data on 340B utilization filled at contract pharmacies as a condition of delivery of 340B-priced drugs to any allowed contract pharmacy. All specified claims data must be submitted on the 340B ESP™ platform within 45 days of the date of dispense.
- The Contract Pharmacy Policy does not apply to covered entities in certain states, as further described in Addendum A.

MTPA is utilizing the 340B ESP™ platform to support contract pharmacy designations and 340B claims data submission. 340B covered entities that have not already registered an account with 340B ESP™ can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab. If you have questions regarding our Contract Pharmacy Policy, please contact us at support@340Besp.com.

In support of a smooth transition to our new distribution model, 340B covered entities



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should work with their contract pharmacy administrators and specialty distributors to process any outstanding Bill To / Ship To replenishment orders in advance of the October 1, 2025, effective date. Our specialty distributors will no longer support distribution of 340B purchased drugs to 340B contract pharmacies after September 30, 2025, other than in compliance with our Contract Pharmacy Policy.

Best regards,

Signed by:
Michael Hirsch
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Michael Hirsch
Executive Director, Market Access, US Commercial Business



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Frequently Asked Questions

Q: Which products are subject to Mitsubishi Tanabe Pharma's policy?

A: Mitsubishi Tanabe Pharma's contract pharmacy policy applies to the NDCs of Radicava ORS (edaravone) included in Addendum B. Mitsubishi Tanabe Pharma will notify covered entities when additional products are added and of other changes to the product list.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Mitsubishi Tanabe's policy?

A: The covered entity may elect to designate a health-system owned or in-network specialty pharmacy as its one contract pharmacy location for Radicava ORS.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing MTPA's drugs, but my entity doesn't use it to dispense MTPA's drugs. Can my entity designate one contract pharmacy instead?

A: Yes, under MTPA's policy, the covered entity may elect to designate a contract pharmacy location registered on the HRSA OPAIS database, regardless of in-house dispensing capabilities, as its single contract pharmacy location.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. No. MTPA's policy allows qualifying 340B covered entities to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q. How often can my covered entity change its contract pharmacy designation?

A. Covered entities may change their contract pharmacy designation once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

Q. How does my covered entity change its contract pharmacy designation?

A. Changes to the single contract pharmacy can only be made by visiting www.340Besp.com/designations. Users that have registered an account with 340B



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ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q. Is Mitsubishi Tanabe Pharma requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A. Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for MTPA to manage its process with its specialty distributors.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: MTPA will not register a HIN on your behalf; however, if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q. How does my covered entity ensure that its eligible contract pharmacy location will take effect on October 1, 2025?

A. For a covered entity's eligible contract pharmacy locations to take effect on October 1, 2025, the entity must designate its contract pharmacy by September 20, 2025. After September 20, 2025, please allow 10 business days for a new or changed eligible contract pharmacy location to take effect.

Q. How long does it take for my covered entity's eligible contract pharmacy location to take effect after October 1, 2025?

A. After October 1, 2025, please allow 10 business days for a new or changed eligible contract pharmacy location to take effect.

Q: How do I submit 340B claims data originating from my single contract pharmacy location designation?

A: 340B covered entities can submit claims under the Contract Pharmacy Policy by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for Radicava ORS by navigating to the Claims Data Submission tab. 340B claims must be submitted within 45 days of the date of dispense for the contract pharmacy to remain eligible to receive 340B purchased drugs.

Q: What happens if my organization does not provide 340B claims by the required date?

A: Failure to provide claims data consistent with the Contract Pharmacy Policy may result



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in the designated contract pharmacy losing eligibility to receive Radicava ORS at the 340B price. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with any questions. Please also ensure that your covered entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with claims data submission. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient.



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ADDENDUM A – Exempted States

In an abundance of caution, MTPA exempts from its Contract Pharmacy Policy covered entity locations in states that have passed legislation that purports to prohibit manufacturers from restricting 340B contract pharmacy utilization, upon such legislation taking effect. MTPA recognizes that many of these state laws are currently subject to litigation, and MTPA reserves the right to modify or remove a state exclusion, including without limitation upon the issuance of a court opinion invalidating the applicable state law.

Questions about this exemption may be directed to support@340BESP.com.



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ADDENDUM B – INCLUDED NDCs

The following NDCs of Radicava ORS are subject to the Contract Pharmacy Policy:

Unit of sale	NDC number	Package configuration
RADICAVA ORS Starter Kit	NDC 70510-2321-1	Carton of One (1) bottle of 35mL (105 mg/5 mL dose)
	NDC 70510-2321-2	Carton of two (2) NDC 70510-2321-1
RADICAVA ORS Kit	NDC 70510-2322-1	Carton of One (1) bottle of 50 mL (105 mg/5 mL dose)