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Shionogi Inc.

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November 15, 2026

Notice Regarding Shionogi Inc.'s Updated 340B Policy

Dear Covered Entity,

I am writing to inform you that Shionogi Inc. is altering its policy regarding eligibility to receive our specialty product Radicava ORS® (edaravone) purchased at the 340B price. The following policy will apply effective December 1, 2026:

What is changing?

Effective December 1, 2026, all 340B covered entities will be required to submit 340B pharmacy and medical benefit claims data for dispenses on or after December 1, 2026, at in-house and contract pharmacies through the 340B ESP™ platform within 45 days of product dispense. Failure to provide claims data under Shionogi's policy may result in loss of access to 340B pricing until the required data is submitted.

In addition, Shionogi will no longer permit 340B covered entities that have an in-house pharmacy capable of dispensing Radicava ORS to eligible patients to designate a single contract pharmacy location. Shionogi will continue to permit any 340B covered entity that does not have an in-house pharmacy capable of dispensing Radicava ORS to designate a single contract pharmacy location, provided the designated contract pharmacy is part of Shionogi'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.

If your covered entity has an in-house pharmacy and currently has a designated contract pharmacy for Radicava ORS, that designation will be deactivated on December 2, 2026, unless your covered entity confirms through 340B ESP that its in-house pharmacy is not capable of

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dispensing Radicava ORS. Covered entities that submit this confirmation by December 1, 2026, will keep their current designation while Shionogi reviews the confirmation. Shionogi may request information to verify the confirmation.

What is not changing?

Shionogi's policy regarding 340B contract pharmacies below otherwise remains unchanged.

Shionogi will continue to 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 Policy does not apply, or applies in a modified form, to covered entities in certain states, as further described in Addendum A.

Shionogi 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.

Best Regards,

Signed by:
Dan Van Horn
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13-Nov-2026 | 12:31:09 PM EST

Dan Van Horn, Senior Vice President of U.S. Market Access

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Frequently Asked Questions

Q: What specifically is Shionogi changing, effective December 1, 2026?

A: Effective December 1, 2026, Shionogi is requiring all covered entities to submit 340B pharmacy and medical benefit claims data for dispenses on or after December 1, 2026, at in-house and contract pharmacies through the 340B ESP™ platform within 45 days of product dispense. In addition, Shionogi will no longer permit 340B covered entities that already have an in-house pharmacy capable of dispensing outpatient drugs to eligible patients to designate an additional single contract pharmacy location.

Q: My covered entity has an in-house pharmacy and already designated a contract pharmacy for Radicava ORS®. What happens to that designation?

A: Effective December 2, 2026, Shionogi will deactivate preexisting contract pharmacy designations for covered entities with an in-house pharmacy capable of dispensing Radicava ORS. If your covered entity's in-house pharmacy cannot dispense Radicava ORS, please confirm this through providing the rationale to support@340Besp.com. Your current designation will stay in place while Shionogi reviews your confirmation. Deactivation under this policy does not count as your covered entity's annual designation change.

Q: How does Shionogi define "in-house pharmacy"?

A: An in-house pharmacy is one owned by the 340B covered entity, parent or child, and identified by HRSA OPAIS under either "Street Address" or "Shipping Addresses".

Q: Which products are subject to Shionogi's policy?

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

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

A: If the covered entity does not have an in-house pharmacy capable of dispensing Radicava ORS, it 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 can purchase and dispense Shionogi drugs, but my entity doesn't use it to dispense Shionogi drugs. Can my entity designate one contract pharmacy instead?

A: No, effective December 1, 2026, a covered entity with an in-house pharmacy may no longer designate a contract pharmacy location registered on the HRSA OPAIS database 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. Shionogi'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.

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

Q: Is Shionogi 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 for a covered entity to designate it as its single contract pharmacy. This information is important for Shionogi 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: Shionogi 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 long does it take for my covered entity's eligible contract pharmacy location to take effect?

A: 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?

A: 340B covered entities can submit claims under Shionogi's 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

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be submitted within 45 days of the date of dispense for the 340B pharmacy or risk losing eligibility 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 Shionogi's policy may result in the in-house or 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, Shionogi exempts from its 340B Policy or modifies its 340B Policy for covered entity locations in states that have passed legislation regarding 340B contract pharmacies, upon such legislation taking effect. A list of these states is below. Shionogi recognizes that many of these state laws are currently subject to litigation, and Shionogi 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.

Arkansas
Colorado
Illinois
Louisiana
Maine
Maryland
Mississippi
Missouri
Nebraska
New Mexico
North Dakota
Oklahoma
Oregon
Rhode Island
South Dakota
Tennessee
Utah
Vermont
Washington
West Virginia

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ADDENDUM B – Included NDCs

The following NDCs of Radicava ORS® are subject to Shionogi's 340B Policy:

Unit of Sale	NDC Number	Package Configuration
RADICAVA ORS Starter Kit	NDC 70510-2321-1	Carton of One (1) bottle of 35 mL (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)