

Effective January 2025, the Non-Opioid Policy for Pain Relief “NOPAIN” Act requires the Centers for Medicare and Medicaid (CMS) to provide temporary separate payment for clinically proven non-opioid treatments in the hospital outpatient and ambulatory surgery settings through December 31, 2027.¹ In the published 2025 Outpatient Prospective Payment System Proposed Rule, CMS has added the ON-Q* elastomeric infusion pump non-opioid pain management delivery system.² If the Proposed Rule is finalized as published, the ON-Q device will be the first and only medical device included under the NOPAIN Act.³



The NOPAIN (Non-Opioids Prevent Addiction in the Nation) Act

- As announced in the Centers for Medicare and Medicaid (CMS) Proposed Rule for CY 2025 Outpatient Prospective Payment System released in July 2024,⁴ the ON-Q device is proposed for approval under the NOPAIN Act and to receive a unique code eligible for separate payment effective January 2025.⁵ This would mark the first time that the ON-Q device would qualify for separate payment.⁶
- The ON-Q device is the only device to date [joined by a short list of drugs]⁷ that has been qualified by CMS under the NOPAIN Act as a treatment that “shows the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal”.⁸
- We at Avanos commend CMS on their efforts of making it easier to provide patients with access to non-opioid therapies. We will continue to work directly with CMS and engage with healthcare professionals to advocate for proven non-opioid treatments through qualified products like the ON-Q device.
- As detailed in the Proposed Rule, final payment methodologies and limitations for all treatments (device^{9,10} and drugs^{11,12}) under the NOPAIN Act will be finalized and published in the CMS CY 2025 OPPI Final Rules¹³ which is historically released late Q4.

More on the NOPAIN Act

- The NOPAIN Act was included as part of the Consolidated Appropriations Act of 2023 and signed into law on December 29, 2022.¹⁴
- Starting January 1, 2025, the NOPAIN Act requires CMS (Medicare) to separately pay for non-opioid treatments (drugs, biologics, devices) that meet the CMS definition for post op pain relief based on FDA documentation, published peer-reviewed literature, or other evidence-based support.¹⁵
- The NOPAIN Act applies only to HOPD and ASC sites of service and therefore, does not apply to Hospital Inpatient or Physician Non-Facility settings of care.¹⁶
- Upon publication of the Final Rule, separate payment under the NOPAIN Act will remain in effect for 3 years; through December 31, 2027.¹⁷ CMS will continue to re-evaluate the bundled payment methodology for post op pain control for implementation after December 31, 2027.¹⁸
- CMS typically publishes the 2025 Final Rule in late Q4. This Final Rule will issue the official rulemaking and guidance to define the process by which applicable non-opioid products are designated for separate payment, the applicable coding and payment methodology, and claims processing effective January 1, 2025.¹⁹
- Click to view the [CMS CY 2025 OPPI Proposed Rule](#) or to learn more about the [NOPAIN Act](#) and the proposed addition of ON-Q to the NOPAIN Act [Proposed Qualifying Products](#).

For more information on ON-Q and the NOPAIN Act, Contact our Market Access and Reimbursement Team at reimbursement@avanos.com.

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- ¹ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy for Pain Relief Under the OPPI and ASC Payment System; Section F, 1: <https://www.federalregister.gov/d/2024-15087/p-1674>
- ² Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section C, 1, page 1683: <https://www.federalregister.gov/d/2024-15087/p-1683>
- ³ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section E, page 1696: <https://www.federalregister.gov/d/2024-15087/p-1696>
- ⁴ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: <https://www.federalregister.gov/documents/2024/07/22/2024-15087/medicare-and-medicaid-programs-OPPI-ASC>
- ⁵ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section E, page 1696: <https://www.federalregister.gov/d/2024-15087/p-1696>
- ⁶ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section C, 2, page 1684: <https://www.federalregister.gov/d/2024-15087/p-1684>
- ⁷ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section E, page 1696: <https://www.federalregister.gov/d/2024-15087/p-1696>
- ⁸ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section C, 1-2, page 1684: <https://www.federalregister.gov/d/2024-15087/p-1684>
- ⁹ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section D, page 1685: <https://www.federalregister.gov/d/2024-15087/p-1685>
- ¹⁰ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section D, page 1694: <https://www.federalregister.gov/d/2024-15087/p-1694>
- ¹¹ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section D, page 1685: <https://www.federalregister.gov/d/2024-15087/p-1685>
- ¹² Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section E, page 1688: <https://www.federalregister.gov/d/2024-15087/p-1688>
- ¹³ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section E, page 1697: <https://www.federalregister.gov/d/2024-15087/p-1697>
- ¹⁴ H.R.2617 - 117th Congress (2021-2022): Consolidated Appropriations Act, 2023. (2022, December 29): <https://www.congress.gov/bill/117th-congress/house-bill/2617>
- ¹⁵ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section C, 1-2, page 1684: <https://www.federalregister.gov/d/2024-15087/p-1684>
- ¹⁶ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section D, page 1686: <https://www.federalregister.gov/d/2024-15087/p-1686>
- ¹⁷ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section D, page 1674: <https://www.federalregister.gov/d/2024-15087/p-1674>
- ¹⁸ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section D, page 1694: <https://www.federalregister.gov/d/2024-15087/p-1694>
- ¹⁹ Centers for Medicare and Medicaid (CMS) CY 2025 Proposed Rule; 89 FR 59186: Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023; Section A, page 1677: <https://www.federalregister.gov/d/2024-15087/p-1677>