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AdvaMed Position Statement Regarding Transition to National Reimbursement Codes May 30, 2023

The Advanced Medical Technology Association (AdvaMed) represents manufacturers of medical devices, digital health technologies, and diagnostic products that transform healthcare through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. Our member companies manufacture lifechanging technologies ranging from cardiovascular and orthopedic implants to cancer diagnostics, surgical instruments, and digital health products.

AdvaMed understands there has been some confusion surrounding our member plans to transition from the acronyms NDC/NHRIC¹ to NRC (National Reimbursement Code). We think it is helpful to clarify that this change is in response to a requirement from the Food and Drug Administration (FDA) and a ten-year old requirement that is now being implemented to remove NDC/NHRIC codes from medical device packaging^{2,3}. We understand FDA is comfortable with medical device manufacturers continuing to use the 11-digit number; the only change is replacing “NDC” or “NHRIC” with “NRC” on the packaging. All the usual numbers for adjudicating a claim will remain the same. In other words, the billing identifier inside the pharmacy system will be unchanged.

Ensuring a smooth transition from the legacy codes (NDC and NHRIC) has been the subject of multiple discussions among FDA, AdvaMed, others within the medical device industry, and other stakeholders for many years. In accordance with the recently announced FDA policy, medical devices manufactured and labeled on or after September 24, 2023 may:

¹ NDC is the acronym for National Drug Code. NHRIC is the acronym for National Health Related Items Code.

² May 21, 2021 FDA Guidance, “Enforcement Policy Regarding Use of National Health Related Item Code and National Drug Code Numbers on Device Labels and Packages (<https://www.fda.gov/media/95794/download>)

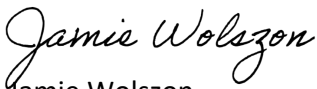
³ From FDA Device Advice website “Legacy Identification Number (NDC/NHRIC): Frequently Asked Questions” (<https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/legacy-identification-number-ndcnhric-frequently-asked-questions>)



- Continue use of the existing 11-digit numbers currently identified as “NDC” on medical device labels for reimbursement purposes or other supply chain purposes.
- Use another term to identify the existing 11-digit numbers.

AdvaMed supports the use of the term National Reimbursement Code (NRC) as a replacement for NDC and NHRIC. Use of this harmonized term among stakeholders will support a smooth transition and minimize impact to patients and other stakeholders.

Respectfully,



Jamie Wolszon

Vice President

Technology & Regulatory Affairs

