

NASPGHAN Washington Report

October 2014

CPSC Bans High-Powered Magnets

On September 24, the Consumer Product Safety Commission (CPSC) voted 4-0 to approve a final safety standard for high-powered magnets. Under the rule, if a magnet set contains a magnet that fits within the CPSC's small parts cylinder, each magnet in the set must have a flux index of 50 or less, otherwise the magnet set would be banned. An individual magnet that is marketed or intended for use as part of a magnet set also must meet these requirements.

The new safety standards will take effect next year – 180 days after publication of the standard in the *Federal Register*.

During the vote proceedings, Commissioner Marietta Robinson said the pediatric gastroenterologists "sounded the alarm" about the dangers of high-powered magnets. She also referenced the first meeting between CPSC and NASPGHAN members on June 12, 2012. At that meeting there were 15 NASPGHAN members who provided case examples of magnet ingestions and appealed for the CPSC's help to prevent ingestions. Commissioner Robinson also praised the testimony of NASPGHAN members (Drs. Mark Gilger, Maria Oliva-Hemker, Ian Leibowitz, Marsha Kay, and Bryan Rudolph) at an October 2013 CPSC public hearing, as well as the survey and data analysis conducted by NASPGHAN members Adam Noel, M.D., and Mazen Abbas, D.O.

Commissioner Robert Adler, also during the vote proceedings, referenced the comments he received in opposition to the safety standard by those who believe the ban of high-powered magnets is an infringement on rights and freedoms. He commented these are the same people who blame caregivers for pediatric ingestions. Adler said he sees little carelessness by caregivers - a comment that was especially poignant given the attendance at the vote of the mother of 19-month-old Annaka Chaffin who died last August after swallowing seven high-powered magnets that her older brother brought home.

Commissioner Joseph Mohorovic noted the final rule is not the end of the issue because there are so many high-powered magnets in the environment. Continued education of the public, both of caregivers and health care professionals, about these magnets and the undistinguishable symptoms of ingestion will be critical to prevent future tragic outcomes.

The safety standard defines magnet sets as "Any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief."

In determining intended uses of a magnet set, the CPSC will consider relevant factors such as the manufacturer's stated intent of the product (such as on a label or website); the content and nature of advertising, promotion, marketing, packaging, or display relating to the product; and the uses for which the product is commonly recognized by consumers.

The definition does not include other magnetic products, such as toys intended for children and jewelry. Magnets that are part of a toy intended for children are already covered by the toy safety standard. Additionally, CPSC does not intend to cover the other types of individual

magnets that are sold for other uses, such as refrigerator magnets, collar stays, or various commercial and industrial uses.

NASPGHAN Comments on Endoscopy Payment Cuts

Last November, the Centers for Medicare and Medicaid Services (CMS) published interim final values for upper endoscopy services which resulted in reimbursement cuts averaging 11 percent, with cuts for some endoscopy services much more severe. On September 2, NASPGHAN submitted [comments](#) to CMS expressing its deep concern with the downstream implications CMS' payment reductions could have on private payer reimbursement for pediatric endoscopy services. In its letter, NASPGHAN echoed concerns raised by the American Gastroenterological Association, the American Society for Gastrointestinal Endoscopy, and the American College of Gastroenterology about how CMS made its determinations for valuation of the endoscopy codes. CMS has stated it intends to finalize the new reimbursement rates for upper endoscopy codes in November with publication of the CY 2015 Medicare Physician Fee Schedule Final Rule.

Medicaid Parity Set to Expire – NASPGHAN Asking for Extension

At the end of 2014, the law requiring enhanced Medicaid rates for primary care services will expire unless Congress decides to pass an extension. The enhanced rates took effect Jan. 1, 2013 as a result of a provision in the Affordable Care Act that requires Medicaid rates in 2013 and 2014 must not be less than the Medicare rates for those years, or, if greater, the Medicare rates that would be applicable in those years using the 2009 conversion factor.

On July 30, Sens. Sherrod Brown (D-OH) and Patty Murray (D-WA) introduced a bill that would extend this Medicaid raise for eligible physicians another two years, through 2016, and make more clinicians eligible for the extra money. Obstetrician-gynecologists, nurse midwives, nurse practitioners, and physician assistants also would become eligible for the higher Medicaid rates under the bill, S. 2694, titled the "Ensuring Access to Primary Care for Women & Children Act." NASPGHAN [endorses](#) this legislation.

In June, NASPGHAN sent a [letter](#) to Senate and House committee leaders asking for at least a two-year extension of the law.

Under the law, higher rates are applied to primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine. The final rule also provides for higher payment for subspecialists related to those specialty categories as recognized by the American Board of Medical Specialties, American Osteopathic Association, and the American Board of Physician Specialties. For example, a pediatric gastroenterologist would qualify for the higher payment if he/she rendered one of the specified primary care services by virtue of that physician's subspecialty within the qualifying specialty of pediatric medicine.

Additionally, physicians who are in those designated specialties but not Board certified (are Board eligible) can also qualify if at least 60 percent of the codes billed by the physician for all of

calendar year 2012 were for the evaluation and management (E&M) codes and vaccine administration codes specified in the final rule.

Codes eligible for the higher payment are E&M codes 99201 through 99499 and vaccine administration codes. This includes codes within the specified range that are not currently covered by Medicare.

NASPGHAN Weighs in on 21st Century Cures Initiative

On June 1, NASPGHAN sent a [letter](#) to Reps. Fred Upton (R-MI) and Diana DeGette (D-CO) who co-chair the House 21st Century Cures Initiative. In its letter, sent in response to the white paper, “21st Century Cures: A Call to Action,” NASPGHAN outlined the need for a greater federal commitment to medical research funding, a reduction in regulatory burdens for individual investigators, and an examination of the pathways by which drugs are tested and approved in children under 18 years. In the letter, NASPGHAN cited the draft guidance for determining whether human research studies can be conducted without an investigational new drug (IND) application as an example of regulatory expansion that could force young investigators to abandon interventional studies or to leave academia.

NASPGHAN Joins Letter to FDA on Biosimilars

In an August 14 [letter](#) to FDA Commissioner Margaret Hamburg, MD, NASPGHAN joined other medical societies and patient advocacy groups to share concerns about the naming of biosimilars. The groups stated that products must have distinguishable, nonproprietary names for the reasons outlined in the letter, including that a biosimilar will only be similar, not identical to the reference product, at least for the foreseeable future. As such, distinct nonproprietary names will help alert physicians that each product, while safe and effective, may differ slightly.

First Round of Physician-Industry Data Released to the Public

The Centers for Medicare and Medicaid Services (CMS) [released](#) on Sept. 30, 2014 the first round of data on consulting fees, research grants, travel reimbursements, and others gifts that medical device manufacturers and pharmaceutical companies provide to physicians and teaching hospitals. In a CMS [press release](#) announcing the program, Dr. Shantanu Agrawal, director of the Center for Program Integrity at CMS, said "Using this new data, it is now possible to conduct a wide range of analyses of payments made by drug and device manufacturers."

Passed as part of the Affordable Care Act, the “Physicians Payments Sunshine Act,” now known as “Open Payments,” requires that certain manufacturers and group purchasing organizations (GPOs) report to CMS information about payments or other transfers of value they’ve made to physicians or teaching hospitals.

As noted in the press release, about 40 percent of the published records are de-identified. This is because a manufacturer had attested that the payment had been made but CMS was unable to match the physician information or the record was not available for review and dispute. This data will be fully identifiable in 2015 after the reporting entity submits corrected data, and physicians and teaching hospitals have a chance to review and dispute. In addition, data that

were disputed and not resolved by the end of the September 11 review period were not published and will be updated at a later date.

According to CMS, the published data contains 4.4 million payments valued at nearly \$3.5 billion attributable to 546,000 individual physicians and almost 1,360 teaching hospitals.

CMS estimates that about 9,000 records were not published due to disputes that weren't settled by the end of the review and dispute period (September 11). Because only 26,000 physicians and 400 teaching hospitals registered in the Open Payments system to review payments attributed to them, questions around the accuracy of the rest of the data could surface once more physicians log into the system to view data attributed to them. Physicians still can [initiate disputes](#) of 2013 data until December 31. However, these disputes will not be flagged in the public database until 2015.

The next published report will include payment data for all of 2014 and will be published in June 2015.