National Home Infusion Association

April 22, 2022

RE: Senate Bill 958 as amended – Medication and Patient Safety Act of 2022

Dear Senators Limon and Portantino,

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed Bill, the *Medication and Patient Safety Act of 2022* (the "Proposed Bill"), sponsored by Senator Limon and Senator Portantino and introduced on February 9 of 2022.[1] NHIA is a trade association that represents companies based in California and across the U.S. that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion community, we write to share our feedback regarding the Proposed Bill.

Statements Pertaining to the Safety and Efficacy of Home Infusion

NHIA disputes the statement made on page 4, subsection (7), lines 14, 15, and 16 claiming that home is "often" not appropriate for the administration of intravenous medications. This statement is not supported by evidence. Several studies demonstrate that home infusion offers patients a safe and effective alternative to facility-based care, particularly for those patients living in rural areas, who have medical conditions making travel difficult, or for whom traveling to an office or facility for infusions is significantly disruptive to their work and/or family life.[2]

Ensuring patient safety is of the utmost importance to home infusion providers. Home infusion services are offered by licensed pharmacists and nurses with specialized training and expertise in preparing and administering intravenous and subcutaneous medications according to independently established standards of practice (I.e. USP <797>, FDA, CDC). Accredited home infusion pharmacies are independently inspected by accreditation organizations and state agencies and must meet industry standards for sterile drug preparation, safe medication administration practices, clinician training and competency, quality assessment and improvement programs, and infection control. NHIA rejects any language in the Proposed Bill (I.e., page 4, lines18, 19, 20) implying home infusion providers are less capable than their office-based colleagues in administering or responding to medication side effects. NHIA acknowledges that

[1] https://trackbill.com/bill/california-senate-bill-958-medication-and-patient-safety-act-of-2022/2223214/

[2] Polinski JM, Kowal MK, Gagnon M, Brennan TA, Shrank WH. Home infusion: Safe, clinically effective, patient preferred, and cost saving. *Healthc (Amst)*. 2017;5(1-2):68-80. Epub 20160429. doi: 10.1016/j.hjdsi.2016.04.004. PubMed PMID: 28668202.

the home site of care can present special challenges which must be accommodated to ensure patient safety. Home infusion providers develop specialized protocols to ensure safety and quality for patients who choose to have medications administered at home. Protocols for each medication administered in the home are developed based on FDA-approved product labeling as well as post-market research to ensure evidence-based resources are available to support all aspects of patient care provided by infusion nurses and pharmacists. The standards of practice promulgated by professional societies that support the delivery of evidence-based patient care applicable in the home infusion practice setting are incorporated into every policy, procedure, protocol and training program developed. Additionally, no care is provided to a home-based patient without specific, detailed written orders from the patient's prescriber that address all aspects of care required for safe and effective home infusion treatment.

Several studies have demonstrated high rates of satisfaction with care, and reveal that patients are rarely discharged from a home infusion service due to an adverse event.[3,4] There is no evidence to support the assumption that office-based settings are safer than the home for infusing and injecting physician-prescribed medications.

Home Infusion Access

With regard to the specific home infusion language in Section 1385.011(b), NHIA agrees with the proposed senate amendments, which allow for infused and injected medications to be administered in the enrollee's home when the physician and patient determine it is in the patient's best interest. NHIA additionally supports amendments that require physicians to inform patients of all payer-supported site-of-care options for receiving infused and injected medications. A similar requirement was recently included in legislation passed by Congress as part of 21st Century Cures.[5] This ensures patients are made aware of all site-of-care options for receiving necessary medications, have the opportunity to discuss the options with their prescriber, and have the ability to choose the site that is most cost-effective and best meets their needs.

Finally, access to home infusion has been essential for patients requiring infused medications during the COVID-19 pandemic. Many high-risk and elderly patients still rely on home infusion to continue life-sustaining treatments while avoiding potential exposure to the virus. Home infusion providers also play a key role in supporting access to life-saving intravenous and subcutaneous monoclonal antibodies for treatment and prevention of severe disease. NHIA

[3] https://nhia.org/wp-content/uploads/2021/10/SUPPLEMENT-Nutrition-ADRs-Sept-Oct.2021-FINAL.pdf
[4] https://nhia.org/wp-content/uploads/2021/10/Supplement.MarApr2021-FINAL.pdf
[5] https://www.congress.gov/bill/114th-congress/house-bill/34

believes that any policy that limits access to home infusion will impair future pandemic preparedness.

Restrictions on Transporting Medications (I.e. Brown Bagging)

NHIA agrees that it is a best practice for the vendor/provider intending to dispense and arrange for—or directly administer an infused medication—to procure, deliver, and prepare such medication. NHIA agrees that medications with special handling requirements should not be transported by patients. NHIA believes this transportation restriction should also apply to physicians who attempt to supply medications to patients for administration at home by a home infusion provider. When a home infusion provider is tasked with coordinating the dispensing, preparation, delivery, and administration of infused medications, the home infusion pharmacy should procure and have control over logistics for arranging care in the patient's home and to ensure accommodations for the home site of care are appropriate.

Conditions for Coverage and Payment of Infused and Injected Medications

NHIA is concerned that the conditions for coverage or payment as described in the Proposed Bill could increase the overall cost of medications for patients. Payers need reasonable flexibility to implement strategies/benefit designs that ensure safe access to infused drugs while managing costs, including patient copays and premiums. Physicians and other ordering practitioners have a significant ability to control where care is delivered. Payer site-of-care optimization strategies have been proven to deliver safe and equally effective care while lowering costs for patients and employers.

NHIA prefers that the legislature limit the scope of the Proposed Bill to restrictions on brown-bagging. However, if the scope of the Proposed Bill maintains restrictions on payer's ability to manage costs through site-of-care strategies, then we recommend removing conditions related to drug "compounding" (page 6, lines 24, 25 in section 135.011). The term "compounding" does not apply in this context. Compounding pertains to the creation of an unapproved drug that has not received approval by the Food and Drug Administration through the new drug application process.[6] The Proposed Bill is aimed primarily at FDA approved drugs, which have preparation and storage instructions included in the approved labeling. Placing conditions on all medications that require any level of aseptic preparation prior to administration is overly broad and unnecessary. Additionally, NHIA requests eliminatation of the condition pertaining to drugs and biologics with risk evaluation and mitigation (REM) strategies. There is no evidence that medications with REM strategies cannot be safely accommodated in settings other than physician offices.

[6] https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies

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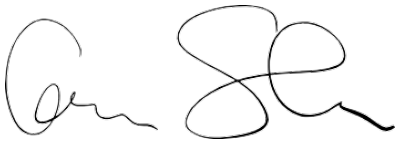
NHIA appreciates the opportunity to provide comments on these important issues and welcomes the opportunity to work with the state of California to improve access to infused and injected medications at the lowest possible cost for all Californians. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,



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