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## Hazardous Drugs: Legislative and Regulatory Efforts to Improve Safe Handling

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### Introduction

When pharmacists, nurses, and other health care workers are occupationally exposed to antineoplastic drugs, they are at risk for a range of toxic effects, including, but not limited to, adverse reproductive outcomes (Connor and McDiarmid, 2006). To address those risks, several organizations have issued safety guidelines regarding the handling of hazardous drugs. The American Society of Hospital Pharmacists (now the American Society of Health System Pharmacists [ASHP]) has published recommendations since 1983 (Stolar, Power, & Viele, 1983) and released its most recent revision in 2006 (ASHP, 2006). The Oncology Nursing Society (ONS) first published guidelines in 1984, and has continued to produce publications and courses on the topic (Polovich, 2011; Neuse et al., 2013; Polovich, Olsen, & LeFebvre, 2014). The Occupational Safety and Health Administration (OSHA) published its first guidelines in 1986 and then updated them in 1996, 1999, and gave guidance as recently as 2016 ([https://www.osha.gov/SLTC/hazardousdrugs/controlling\\_occx\\_hazardousdrugs.html](https://www.osha.gov/SLTC/hazardousdrugs/controlling_occx_hazardousdrugs.html)). The National Institute for Occupational Safety and Health (NIOSH) reviewed the research in this area and issued recommendations for how to handle hazardous drugs in 2004 (Centers for Disease Control and Prevention, 2004). A forthcoming update is anticipated to include the hundreds of studies done since that time and make recommendations based on a growing body of evidence that there are adverse effects from occupational exposure to hazardous drugs.

While federal agencies recognize the NIOSH recommendations, they defer regulation to state governments. In a few states during the last decade, nurses and other advocates have successfully fought for safe-handling legislation that gives the NIOSH recommendations the force of law. Washington state was the first to act, enacting a law in 2011 that covers all medications defined as hazardous by NIOSH. California passed a similar law in 2013, which covers antineoplastic drugs only. North Carolina passed a safe-handling law in 2014 – although, as we discuss below, the rulemaking process was unsuccessful, and that state’s law is now effectively a dead letter. Safe-handling bills are currently advancing in the legislatures of Massachusetts, Michigan, and New Jersey.

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In the brief case studies that follow, we present three different examples of states moving recommendations into policy.

### **Washington: The Pioneer Effort**

In 2010, investigative reporter Carol Smith had been researching the dangers of hazardous drugs and met an advocate named Chelsea Crump (Smith, 2010). Chelsea recounted how her mother, Sue Crump, had been diagnosed with cancer after working as a pharmacist for many years with minimal protection from hazardous drugs. Indeed, even while Sue underwent treatment for her cancer, Chelsea noted that the nurses were not wearing the recommended personal protective equipment, despite national guidelines.

Armed with this story, Chelsea approached two state legislators and asked for a state law that would require healthcare facilities to follow the NIOSH guidelines. In 2011, Governor Christine Gregoire signed two bills into law: one requiring the adoption of NIOSH guidelines for all institutions where hazardous drugs were handled, and the other to maintain a database of personnel who handle hazardous drugs (Eisenberg, 2016). While such databases exist in Europe, none had previously been required in the United States.

The Washington State hazardous drug law was given to the Department of Labor and Industries (L&I) to develop the rule-making process. A multidisciplinary Hazardous Drug Advisory Committee was formed, with members representing employers and employees from large hospitals, retail pharmacies, and private medical practices. Disciplines included pharmacists, industrial hygienists, physicians, nurses, and a representative from a manufacturer of Closed System Transfer Devices (CSTDs). The road to implementation was filled with resistance, particularly from employers who felt the NIOSH guidelines were too restrictive and would be too costly to implement. Several versions of the rules were written and revised, and the original timeline for implementation was lengthened to allow for hospitals to budget for costly pharmacy renovations related to required ventilator controls. As Seth Eisenberg, one of the three nursing members of the worker sub-committee, commented at the end of one tumultuous meeting, "If it had been easy and cheap, they would have done this a long time ago."

The hazardous drug rule was officially adopted by L&I on January 3, 2012. The implementation timeline was divided into three stages: Stage I required each organization to develop and implement a hazardous drug control program by January 1, 2015. Stage 2 required employers to provide hazardous drug training by July 1, 2015. And Stage 3 required hospitals to install appropriate ventilation and biologic safety cabinets by January 1, 2016 (Hazardous Drug, 2016). Despite being the first state to pass a hazardous drug law, L&I has not yet instituted routine inspections of healthcare facilities.

### **North Carolina: The Pitfalls of Rulemaking**

In North Carolina legislative work which began in 2013 advanced as far as law (2014) but the rule that resulted (2015) is not currently enforceable. Legislative work in North Carolina was initiated by the policy arm of a national medical device company, which invested in a local law firm with extensive expertise in regulation and healthcare. With their support,

individual nurses and pharmacists, representatives of healthcare facilities, and state and national advocates were invited to discuss legislation in the Spring of 2013. Following in the footsteps of California with a focus only on anti-neoplastic drugs, HB644 was drafted. Those invited to the table to discuss the effort sought buy-in from the local chapters of the Oncology Nursing Society and the North Carolina Nurses Association and vested individuals. Op-eds were written in the local newspapers and calls to local officials were made. Slight revisions were made to the bill's language and it passed in the NC House in 2013. In July of 2014, the bill passed in the Senate (An Act Related to the Handling of Antineoplastic Agents, 2014). The bill mandated that a group of stakeholders, including nurses, be convened as the North Carolina Department of Labor developed rules for the enforcement of the law. Over the course of 2015, the NC Department of Labor held two public forums and one public comment period, but to the dismay of those invested in the issue, a true stakeholder group was never formed. The rules were published in the fall of 2015 and read that the NIOSH recommendations should be followed unless they were in conflict with state-specific rules codified in the North Carolina Administrative Code or any federal code, in which case the current code should supersede the NIOSH recommendations (North Carolina Office of Administrative Hearings, 2015). Recognizing that this was not a measurable change and that a true stakeholder group had not been convened, advocates sent 21 letters of opposition within 24 hours of the publication of the rules. According to North Carolina law, when at least ten letters of opposition are sent after rules are published, the topic is sent back to the legislature for further review. Strategic conversations are taking place in North Carolina now about how best to proceed with this effort.

### **Michigan: New Legislative and Regulatory Paths**

In Michigan, both legislative and regulatory efforts have advanced. In March 2015, after conferring with a broad coalition of oncology nurses, pharmacists, and industry partners, Senator Jack Brandenburg (R-Harrison Township) introduced Senate Bill 237 with two Republican co-sponsors (Michigan Senate, 2015). The bill contains language similar to the bill enacted in Washington State. At press time, the bill has been referred to the Health Policy Committee; no hearing has been scheduled. Oncology Nursing Society members have met with state legislators and penned op-eds in local papers to encourage consideration of the bill.

Distinct from the legislative effort, the Michigan Occupational Safety and Health Administration (MiOSHA) has launched a program focused on hazardous drugs (Michigan Occupational Safety and Health Administration, 2016). This new program has been informed by survey data obtained from members of the Oncology Nursing Society who reside in Michigan (He, Mendelsohn-Victor, McCullagh, & Friese, 2016). Launched in June 2016, the program consists of outreach and education to affected employers, followed by 12 planned programmed inspections by MiOSHA's industrial hygienists. Identified worksites include facilities where hazardous drugs are prepared and administered, including oncology practices, non-oncology infusion centers, urology offices, and veterinary offices. The inspections will focus on state and federal guidance that minimize the exposure to hazardous drugs and adherence to established standards.

## Next Steps

What if you don't live in one of the states taking legislative action but want to promote policies that support safer handling of antineoplastic and/or hazardous drugs? First, take a look at the policies within your own hospital or clinic. Are they consistent with current NIOSH recommendations? If not, consider a practice group working on moving your clinical area into compliance (Walton et al., 2012). Be aware that in 2018, the United States Pharmacopeial Convention's new Chapter 800, which covers hazardous-medication handling, will be enforceable by the Food and Drug Administration and state boards of pharmacy (Polovich, 2017). State boards of pharmacy will need to consider harmonizing regulations with the requirements of USP 800. Get involved with your professional organizations- your local ONS chapters, your state based nursing organizations and tell those advocating for you that these are issues you care about. Work with others within and outside of nursing to advocate for change in your state if you decide to pursue legislative efforts. Consider as well regulatory approaches like those in Michigan.

As a nurse, you are a well-trained educator. Consider educating your legislators and the public about this issue through letters, calls, visits and writing op-eds for local newspapers. When educating, share personal stories and be prepared to meet some resistance from those within and outside of nursing about associated costs and workflow changes. Most of all, get involved and help make the changes you want to see in your state and for the safety of all of those who come into contact with hazardous drugs.

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**At a Glance**

- Safety guidelines for handling of hazardous drugs exist but are rarely enforced from a regulatory standpoint.
- The authors share their legislative and regulatory experiences in North Carolina, Washington, and Michigan.
- Counsel is given to those looking to be active in legislative and regulatory efforts in their states.

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