

OSHA Hazard Communication

Compounders who have read USP <800> carefully are aware there is a mandate for a “Hazard Communication Program,” but few of them understand the business risk of failing to create one. This post will clarify the following aspects of a Hazard Communications Program:

Its meaning and definition.

Whereas USP <800> has virtually no compliance impact unless enforced by a poorly-informed state pharmacy board, a Hazard Communication Program is a genuinely enforceable federal regulation you can (and should) read about at [29 CFR 1910.1200](#). The purpose of the regulation is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The rationale is that nobody should labor in a workplace with known chemical hazards without being informed of those hazards. The regulation requires the suppliers of products that contain hazardous chemicals to label those products in a very specific manner and provide Safety Data Sheets (formerly called Material Safety Data Sheets) to purchasers. Employers must subsequently ensure this information is further transmitted to their employees by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

Its scope

The requirement for Hazard Communication applies to all employers who have a workforce that spends time in their workplace. This (obviously) encompasses all pharmacies, physician offices, veterinary establishments, hospitals, surgery centers, and extended care facilities. Because pharmacists think first of drugs, many are not focused on chemicals for cleaning, disinfection, and killing spores, but our program must cover those also. Compounding pharmacies generally keep bulk quantities of active pharmaceutical ingredients and virtually all such API come with Safety Data Sheets.

Its legal basis and federal and state entities that enforce its compliance.

The requirement for employers to create and maintain a Hazard Communication Program is a mature federal regulation that has been in place since 1994 and the governing case law is well established. OSHA can delegate the enforcement of the federal regulations to the various state governments if they successfully navigate the process of establishing an OSHA-Approved State Plan. Twenty-two states have OSHA-Approved State Plans for private workers as well as workers employed by state and local government (see Table A). State Plans, once approved, may have the power to impose stiffer sanctions than those of OSHA. Note that virtually all states have a governmental arm that enforces STATE Occupational Safety and Health statutes and agencies, but which can enforce the FEDERAL statute only if they are OSHA Approved State Plans

California	Arizona	North Carolina
Iowa	Tennessee	Maryland
Virginia	Michigan	Minnesota
Nevada	Kentucky	New Mexico
Oregon	Indiana	South Carolina
Utah	Hawaii	Puerto Rico
Vermont	Wyoming	Washington
	Alaska	

Operational Requirements

So, to ensure their operations comply with the Hazard Communication regulation, what must a company do?

Develop and maintain a **written** hazard communication program for the workplace, that includes:

- A **List** of hazardous chemicals present.
- Accurate **labeling** of containers of chemicals in the workplace, as well as of containers of chemicals being shipped from your workplace to **other workplaces**.
- Demonstrable preparation and **distribution** of safety data sheets to employees and **downstream employers**. and
- Development and **implementation** of employee **training** programs regarding hazards of chemicals and protective measures.

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To dive deeper:

“List” means that if you keep a chemical in your workplace which is covered by a Safety Data Sheet you must have proof that you are tracking it in your Hazard Communication Program.

“Labeling” means just what it says. If you buy a commercial product, it will have labeling in the fine print on the side of the container, but when you subdivide quantities into smaller containers, it could be construed that the smaller containers must echo the cautionary labeling of the “parent” container.

“Distribution” of SDS means you must demonstrate that your employees have ready access to any product included on your “List.” This can be a three-ring binder, a file cabinet or (since this is the electronic age) it can be accomplished by a subscription to a web-based SDS database. The last one I subscribed to (years ago) was www.msds.com. I entered its URL in a browser and learned that their subscription costs \$199 per year. A broader Google [search](#) yielded several competitive web based services that I did not take time to evaluate.

“Training” means that you must ensure that all employees undergo training that informs them of the list of hazardous chemicals present, how to comprehend and interpret product labeling and how to locate and read the SDS for each substance on the list. This training should be successfully completed upon hire and before performing work activities. It should also be “refreshed” on a regular basis, the logical timing of which could coincide with your refresher training for HIPAA, Universal Precautions, etc. Training needs to ensure that employees comprehend and can competently execute the protocol for responding to exposures and spills, including location and use of spill remediation materials.

Likely triggering events

Unlike the FDA, OSHA rarely makes random inspections. More than half of OSHA drop-ins are complaint/event based. In my experience, the triggering event for pharmacies and physician practices is most likely a complaint filed by a current or former employee. About 20% of such complaints result in an inspection, but the likelihood is higher in target industries or if the complaint touches on hot topics.

Optimal Compliance Strategies

For years, I have advised my healthcare clients that having a robust and deliberate Hazard Communication Program is tantamount to a “litmus test” for OSHA. It forms their impression of whether you “get it” or you don’t. Recently I learned that one of my business partners had an OSHA inspection at a pharmacy he formerly owned and could bear witness to the value of incorporating effective Hazard Communication into your SOPs. As soon as we can schedule it, we’re going to record a conversation about his remarkable OSHA experience which we will post to 503qm.com.

KEY TAKE AWAY

If OSHA “comes knocking on your door,” one of their earliest questions will be about your Hazard Communication Program. The *right answer* is, “Let me boot up my computer and I will show you how to review our List, our training program, our attestation tracking, and how to log on to our SDS database. Or would you rather I print the list and we can walk around and look at our storage practices and spill resources? Either way we’re glad you’re here because we’re eager to improve.” The *WRONG ANSWER* is, “What is a Hazard Communication Program?”