

# Medication Safety

## Statutory Protection for Medication-Error Reporting (1505)

Source: Council on Public Policy

To collaborate with other healthcare providers, professions, and stakeholders to advocate and support state and federal legislative and regulatory initiatives that provide liability protection for the reporting of actual and potential medication errors by individuals and healthcare providers; further,

To provide education on the role that patient safety organizations play in liability protection.

*This policy supersedes ASHP policy 0011.*

## Support for Second Victims (1524)

Source: Council on Pharmacy Practice

To acknowledge that the patient is the primary victim in any medical error, unanticipated adverse patient event, or patient-related injury; further,

To acknowledge that involvement by healthcare personnel in such events may cause them to become second victims; further,

To recognize that a just culture and a healthy culture of safety embrace a support system for second victims; further,

To encourage healthcare organizations to establish programs to support second victims; further,

To educate healthcare professionals (including those in training), health organization administrators, and regulatory agencies about the second-victim effect and available resources.

## Standardization of Small-Bore Connectors to Avoid Wrong-Route Errors (1530)

Source: Council on Pharmacy Practice

To support the use of medication administration device connectors and fittings that are designed to prevent misconnections and wrong-route errors; further,

To encourage healthcare organizations to prepare for safe transition to use of medication delivery device connectors and adapters that meet International Organization for Standardization standards; further,

To identify and promote the implementation of best practices for preventing wrong-route errors.

*This policy supersedes ASHP policy 1018.*

## Just Culture (1115)

Source: Council on Pharmacy Practice

To recognize that the principles of *just culture* promote an environment in health care organizations in which safety is valued, reporting of safety risks is encouraged, and a fair process is used to hold staff and leaders accountable; further,

To encourage hospitals and health systems to include *just culture* as a component in organizational safety culture surveys and quality improvement initiatives.

*This policy was reviewed in 2015 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

## Just Culture and Reporting Medication Errors (1021)

Source: Council on Pharmacy Practice

To encourage pharmacists to exert leadership in establishing a just culture in their workplaces and a nonpunitive systems approach to addressing medication errors while supporting a nonthreatening reporting environment to encourage pharmacy staff and others to report actual and potential medication errors in a timely manner; further,

To provide leadership in supporting a single, comprehensive, hospital- or health-system-specific medication error reporting program that (1) fosters a confidential, nonthreatening, and nonpunitive environment for the submission of medication error reports; (2) receives and analyzes these confidential reports to identify system-based causes of medication errors or potential errors; and (3) recommends and disseminates error prevention strategies; further,

To provide leadership in encouraging the participation of all stakeholders in the reporting of medication errors to this program.

(Note: A just culture is one that has a clear and transparent process for evaluating errors and separating events arising from flawed system design or inadvertent human error from those caused by reckless behavior, defined as a behavioral choice to consciously disregard what is known to be a substantial or unjustifiable risk.)

*This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

## Minimizing the Use of Abbreviations (0604)

Source: Council on Administrative Affairs

To support efforts to minimize the use of abbreviations in health care; further,

To collaborate with others in the development of a lexicon of a limited number of standard drug name abbreviations that can be safely used in patient care.

*This policy was reviewed in 2015 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

## Drug Names, Labeling, and Packaging Associated with Medication Errors (0020)

Source: Council on Professional Affairs

To urge drug manufacturers and FDA to involve practicing pharmacists, nurses, and physicians in decisions about drug names, labeling, and packaging to help eliminate (a) look-alike and sound-alike drug names, and (b) labeling and packaging characteristics that contribute to medication errors; further,

To inform pharmacists and others, as appropriate, about specific drug names, labeling, and packaging that have documented association with medication errors.

*This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

## ASHP Policy Positions 2009–2019 (with Rationales): Medication Safety

**1505**

### **STATUTORY PROTECTION FOR MEDICATION-ERROR REPORTING**

*Source: Council on Public Policy*

To collaborate with other healthcare providers, professions, and stakeholders to advocate and support state and federal legislative and regulatory initiatives that provide liability protection for the reporting of actual and potential medication errors by individuals and healthcare providers; further,

To provide education on the role that patient safety organizations play in liability protection.

*This policy supersedes ASHP policy 0011.*

#### ***Rationale***

Medication-error reporting at the state and federal level has been shown to improve medication-use systems and aid in conducting a root cause analysis of a medication error. Liability protection for such reporting at the federal is necessary to achieve this analysis and improve patient safety. Pharmacists need to be aware of legal protection for error reporting under the federal Patient Safety and Quality Improvement Act of 2005. The Act set up a network of federally sanctioned [Patient Safety Organizations](#) (PSOs) that provide protection for healthcare providers, including pharmacy personnel. A PSO is prohibited from identifying individuals or organizations that report and the information used for educational purposes must be de-identified, including contextually as necessary. The Act overrides state protections and supports the collaboration sought among providers who report and work with a PSO.

**1524**

### **SUPPORT FOR SECOND VICTIMS**

*Source: Council on Pharmacy Practice*

To acknowledge that the patient is the primary victim in any medical error, unanticipated adverse patient event, or patient-related injury; further,

To acknowledge that involvement by healthcare personnel in such events may cause them to become second victims; further,

To recognize that a just culture and a healthy culture of safety embrace a support system for second victims; further,

To encourage healthcare organizations to establish programs to support second victims; further,

To educate healthcare professionals (including those in training), health organization administrators, and regulatory agencies about the second-victim effect and available resources.

**Rationale**

The [University of Missouri Health System](#) has defined second victims as “healthcare providers who are involved in an unanticipated adverse patient event, in a medical error and/or a patient-related injury and become victimized in the sense that the provider is traumatized by the event.” Frequently, these individuals feel personally responsible for the patient outcome. Many feel as though they have failed the patient, second-guessing their clinical skills and knowledge base. Individuals involved in a serious adverse patient event may experience the symptoms of post-traumatic stress disorder and may require support to successfully manage the experience.

Healthcare organizations have emphasized establishing a just culture environment to encourage individuals to speak up when they are aware of medication errors. Studies have indicated that many second victims did not feel they received organizational support after these events, however. The Joint Commission, the [Institute for Healthcare Improvement](#), the [Institute for Safe Medication Practices](#) (ISMP), and others have advocated for support systems for second victims. The Joint Commission Leadership Standards state that leaders will “make support systems available for staff that have been involved in an adverse or sentinel event.”

Healthcare organizations will have to tailor these support system to their needs. Such support systems may, for example, be tiered, with the first tier being unit or department support; the second tier, trained peer support, including patient-safety and risk-management staff; and the third tier, professional counseling support, such as employee assistance programs or social workers. Education of staff on resources available to support the second victim is critical to avoiding adverse impact on the second victim.

**1530****STANDARDIZATION OF SMALL-BORE CONNECTORS TO AVOID WRONG-ROUTE ERRORS**

*Source: Council on Pharmacy Practice*

To support the use of medication administration device connectors and fittings that are designed to prevent misconnections and wrong-route errors; further,

To encourage healthcare organizations to prepare for safe transition to use of medication delivery device connectors and adapters that meet International Organization for Standardization standards; further,

To identify and promote the implementation of best practices for preventing wrong-route errors.

*This policy supersedes ASHP policy 1018.*

**Rationale**

Interconnectivity among drug delivery devices and their fittings is a significant and preventable cause of serious or fatal wrong-route errors. Connector and tubing design unique to the route of administration that cannot be linked to a device used for a different route is the strongest

type of control for these errors.

An international joint working group composed of the [International Organization for Standardization \(ISO\)](#), [Association for the Advancement of Medical Instrumentation \(AAMI\)](#), FDA, manufacturers, clinicians, and other regulators recently initiated development of [new ISO connector standards](#) for medical devices for intravascular/hypodermic, limb cuff, enteral, neuraxial, and breathing systems/pressurized medical gas applications. Urethral standards are also planned, but not yet initiated. The new ISO standards are voluntary and intended to facilitate global standardization of medical devices. The FDA has announced that it will only approve or clear an enteral device with a new small-bore connector if it meets the ISO standard or equivalent alternative method. (Small-bore [less than 8.5 mm diameter] connectors are used to link or join devices, accessories, and components for intravascular/hypodermic, neuraxial [epidural, intrathecal, spinal], urinary, enteral, and breathing system/medical gas delivery of medications.) Subsequently, the first ISO standard for enteral device connectors ([ANSI/AAMI/ISO 80369-1](#)) has been adopted industrywide. New connectors will be phased in, beginning fourth quarter 2014. The Joint Commission recently published Sentinel Event Alert #53, [Managing risk and transition during transition to new ISO tubing connector standards](#). The alert provides suggested actions from the 2014 *Get Connected* campaign provided by the Global Enteral Device Supplier Association (GEDSA), as well as updates to the recommendations from the 2006 Sentinel Event Alert #36 on tubing misconnections.

In addition, the following statements were issued from the 2008 Global Conference on the Future of Hospital Pharmacy in Basel, Switzerland:

Pharmacists should ensure that strategies and policies are implemented to prevent wrong route errors, including, for example, labeling of intravenous tubing near insertion site to prevent misconnections, and use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines.

Oral syringes that are distinctly different from hypodermic syringes should be used to prevent injection of enteral or oral medicines, especially in pediatric patients.

## 1115

### JUST CULTURE

*Source: Council on Pharmacy Practice*

To recognize that the principles of *just culture* promote an environment in health care organizations in which safety is valued, reporting of safety risks is encouraged, and a fair process is used to hold staff and leaders accountable; further,

To encourage hospitals and health systems to include *just culture* as a component in organizational safety culture surveys and quality improvement initiatives.

### **Rationale**

The Council, Board, and House agreed that a specific ASHP policy supporting *just culture* principles should be developed, and that education on the topic should be an important focus for ASHP. In developing the policy, the Council reviewed principles and methods established by

David Marx, a systems safety engineer and *just culture* educator, and noted the following (Marx, D. *Whack-a-Mole: The Price We Pay for Expecting Perfection*. Plano, TX: By Your Side Studios; 2009):

- The notion that humans can perform perfectly if they are well trained and continuously vigilant is unrealistic. Humans will never be perfect.
- Safe environments anticipate human error and systems are designed accordingly. However, systems will never be perfect.
- Individuals are accountable for behavioral choices that lead to error and leaders are accountable for establishing environments that encourage reporting of unsafe conditions and adverse events.
- Behaviors that cause or may cause errors are addressed regardless of whether harm occurs.
- Individual culpability for adverse events is assessed using a decision algorithm that defines attributes of behaviors and systems and can be summarized as follows:
  1. **Human error:** inadvertent; a mistake; doing other than what should have been done.  
**Origin:** System design, processes, procedures, training.  
**Manage by:** correcting system, supporting employee.
  2. **At-risk behavior:** behavioral choice that increases risk where risk is not recognized or is mistakenly believed to be justified.  
**Origin:** System inefficiencies, such as steps that create rework, are burdensome, or seem irrelevant to outcome. The system incentivizes workarounds and shortcuts that are unsafe.  
**Manage by:** Improving procedures or processes to remove incentives and reward safe behaviors.
  3. **Reckless behavior:** choosing to behave in a manner that places others at substantial and unjustifiable risk knowing that harmful outcome is likely but indifferent to it.  
**Origin:** the individual.  
**Manage by:** remedial action, punitive action.
  4. **Negligence:** determined by using the substitution test, i.e., would another individual in the same work area with comparable experience and qualifications have behaved any differently?

The Council identified significant advantages to this approach, one of the most important being that it encourages reporting of adverse events and provides essential information for improving systems and processes of care. In addition, holding individuals accountable by using criteria to distinguish between behaviors that do or do not merit punishment was perceived to be the fairer approach than a strictly punitive or strictly blame-free approach. Another positive attribute of *just culture* is that behaviors associated with error are handled with the appropriate responses regardless of whether harm resulted. By focusing on behaviors rather than outcomes, potential errors are averted, safe behaviors are encouraged, and at-risk or reckless behavior is not tolerated.

The Council recognized that while the *just culture* approach has been accepted by safety leaders, implementation is challenging for a number of reasons. The goals of *just culture*--to sustain a nonpunitive reporting and learning environment, yet hold individuals accountable for their behavior--seem contradictory. Methods for differentiating behaviors for which to hold an individual accountable tend to use subjective, rather than objective, criteria, and may lead to misinterpretation. Maintaining the *just culture* approach is particularly challenging under the pressure of media coverage and legal liability when a patient is harmed or dies from an error. The belief that individual practitioners are solely responsible for their errors continues to predominate in the health care professions.

The Council noted that decision-making tools and education are available to support implementation of a *just culture*. They suggested that ASHP consider providing education and practical tools for implementing fair processes for holding individuals and leadership accountable for medication safety. Council members also characterized *just culture* as a component of the larger issue of culture of safety and proposed that assessment of *just culture* as part of assessing general safety culture should be included in ASHP's national survey.

## 1021

### JUST CULTURE AND REPORTING MEDICATION ERRORS

*Source: Council on Pharmacy Practice*

To encourage pharmacists to exert leadership in establishing a just culture in their workplaces and a nonpunitive systems approach to addressing medication errors while supporting a nonthreatening reporting environment to encourage pharmacy staff and others to report actual and potential medication errors in a timely manner; further,

To provide leadership in supporting a single, comprehensive, hospital- or health-system-specific medication error reporting program that (1) fosters a confidential, nonthreatening, and nonpunitive environment for the submission of medication error reports; (2) receives and analyzes these confidential reports to identify system-based causes of medication errors or potential errors; and (3) recommends and disseminates error prevention strategies; further,

To provide leadership in encouraging the participation of all stakeholders in the reporting of medication errors to this program.

*(Note: A just culture is one that has a clear and transparent process for evaluating errors and separating events arising from flawed system design or inadvertent human error from those caused by reckless behavior, defined as a behavioral choice to consciously disregard what is known to be a substantial or unjustifiable risk.)*

*This policy supersedes ASHP policy 0910.*

### **Rationale**

"Just culture" is an approach to medical error management that recognizes individual accountability for behavioral choices that compromise safety. The concept of "just culture" was first introduced by Sidney Dekker, a pilot and systems engineer, who recommended a different

approach to the view that management of medical error should take a strict systems approach with a “no blame” attitude regarding individual accountability. David Marx, a lawyer and engineer, added additional background and recommendations, including criteria for determining whether error is “human” (i.e., inadvertent and unintended) or the result of behavioral choices that introduce risk.

“Just culture” differs from the “no blame” approach in two ways: (1) intentional actions that introduce risk or lead to error are acknowledged, and (2) an algorithm or criteria are used to determine the type of corrective action that should be taken (e.g., coaching or disciplinary action). “Just culture” has come to be accepted over the “no blame” approach because it allows the safety and health care community to address what Dekker and Marx characterize as at-risk and reckless behavior as causes of error.

**Medication Errors and Risk Management (0021)**

*Source: Council on Professional Affairs*

To urge that pharmacists be included in health care organizations' risk management processes for the purpose of (a) assessing medication-use systems for vulnerabilities to medication errors, (b) implementing medication-error prevention strategies, and (c) reviewing occurrences of medication errors and developing corrective actions.

*This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Human Factors Concepts (9609)**

*Source: Council on Professional Affairs*

To encourage pharmacists to apply human factors concepts (human errors related to inadequate systems or environment) in the prevention, analysis, and reporting of medication errors; further,

To encourage research (in conjunction with other groups, as appropriate) to identify human factors causes of medication errors and opportunities for their prevention.

*This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*