

## The Patient Safety and Quality Improvement Act of 2005 (PSQIA)

The Patient Safety and Quality Improvement Act of 2005 (“PSQIA”) amended Title IX of the Public Health Service Act for purposes of improving patient safety and reducing the occurrence of adverse events. The PSQIA creates a voluntary program for providers to share information relating to patient safety events with patient safety organizations and imposes confidentiality and privilege requirements on such reported information to encourage providers to share the information without fear of liability.

### 1.) Defining New Terms

The PSQIA and the regulations implementing the Act<sup>1</sup> created new terms to identify the type of information covered by the privilege, and to describe the elements of the voluntary reporting program and the organizations and individuals involved and impacted.

#### a.) WHAT INFORMATION IS PROTECTED?

The PSQIA defines patient safety work product (“PSWP”) as data, reports, records, memoranda, analyses, or statements<sup>2</sup> that satisfy any of the following criteria:

- Could result in improved patient safety, health care quality, or health care outcomes, are assembled or developed by a provider for reporting to a patient safety organization and, are reported to a patient safety organization;<sup>3</sup>
- Could result in improved patient safety, health care quality, or health care outcomes, and are developed by a patient safety organization for the conduct of patient safety activities;<sup>4</sup> or
- Identify or constitute deliberations or analysis of, or identify the fact of reporting to, a patient safety evaluation system.<sup>5</sup>

PSWP does not include a patient’s medical record, billing and discharge information, or any other original patient or provider record,<sup>6</sup> nor does it include information that is collected, maintained,

<sup>1</sup> Adopted in final form on November 21, 2008. Available at 42 CFR Part 3, p. 70796.

<sup>2</sup> PSQIA, 42 U.S.C. § 299b-21(7)(A).

<sup>3</sup> PSQIA, 42 U.S.C. § 299b-21(7)(A)(i)(I). Note: information that is not yet reported to a PSO, but is documented within the provider’s patient safety evaluation system and that will be reported to a PSO in the future is considered PSWP; providers may voluntarily remove information from such system prior to its reporting, at which point, the information would no longer be considered PSWP (42 CFR Part 3, p. 70733).

<sup>4</sup> PSQIA, 42 U.S.C. § 299b-21(7)(A)(i)(II).

<sup>5</sup> PSQIA, 42 U.S.C. § 299b-21(7)(A)(ii).

<sup>6</sup> PSQIA, 42 U.S.C. § 299b-21(7)(B)(i).

developed or existing separately from a patient safety evaluation system.<sup>7</sup> Identifiable PSWP is limited<sup>8</sup> to PSWP that contains HIPAA-type individually identifiable information,<sup>9</sup> or that could identify any of the following entities:

- The provider that is the subject of the work product;<sup>10</sup>
- Any providers that participated in activities that are the subject of the work product;<sup>11</sup>
- An individual<sup>12</sup> who reported information to a provider with the intent of having such information reported to a patient safety organization;<sup>13</sup> or
- An individual who reported information directly to a patient safety organization.<sup>14</sup>

PSWP will be considered non-identifiable with respect to an identified provider or reporter under the following circumstances:

- An appropriate person, applying applicable principles and methods, documents a determination that the risk of the information being used by a recipient to identify a provider or reporter is very small;<sup>15</sup> or
- Direct identifiers are removed;<sup>16</sup> and the entity making the disclosure does not have actual knowledge that the information could be used in any way to identify the particular provider or reporter.<sup>17</sup>

A provider, PSO, or responsible person may assign a means of record identification to allow information made non-identifiable to be re-identified by such party, if the means of record identification is not capable of being translated to identify the provider or reporter,<sup>18</sup> and the party does not otherwise use or disclose the means of record identification.<sup>19</sup> PSWP is non-identifiable with respect to a particular patient only if the individually identifiable health information regarding the patient is de-identified in accordance with HIPAA.<sup>20</sup>

---

<sup>7</sup> PSQIA, 42 U.S.C. § 299b-21(7)(B)(ii). Note: just because such separate information is reported to a patient safety organization does not make the information PSWP by virtue of its reporting alone.

<sup>8</sup> PSQIA, 42 U.S.C. § 299b-21(3).

<sup>9</sup> PSQIA, 42 U.S.C. § 299b-21(2)(B).

<sup>10</sup> PSQIA, 42 U.S.C. § 299b-21(2)(A).

<sup>11</sup> PSQIA, 42 U.S.C. § 299b-21(2)(A).

<sup>12</sup> PSQIA, 42 U.S.C. § 299b-21(2).

<sup>13</sup> PSQIA, 42 U.S.C. § 299b-22(e)(1)(A).

<sup>14</sup> PSQIA, 42 U.S.C. § 299b-22(e)(1)(B).

<sup>15</sup> 42 CFR § 3.212(a)(1).

<sup>16</sup> 42 CFR § 3.212(a)(2)(i).

<sup>17</sup> 42 CFR § 3.212(a)(2)(ii).

<sup>18</sup> 42 CFR § 3.212(a)(3)(i).

<sup>19</sup> 42 CFR § 3.212(a)(3)(ii).

<sup>20</sup> 42 CFR § 3.212(b). Note: The HIPAA standard and implementation specifications for de-identification are found at 45 CFR 164.514(a) through (c).

## **b.) WHAT ENTITIES ARE INVOLVED WITH THE COLLECTION AND REPORTING OF PSWP?**

The entities impacted by the PSQIA include patient safety organizations and providers.<sup>21</sup> A provider is an individual or entity authorized under state law to provide health care services.<sup>22</sup> This definition includes affiliated providers, which are legally separate providers that fall into one of three categories:<sup>23</sup>

- The parent organization of the provider;
- Entities under common ownership, management, or control with the provider; or
- Entities owned, managed, or controlled by the provider.

A patient safety organization, or PSO, is a public or private entity (or component thereof) listed by the Department of Health and Human Services (“HHS”) as a PSO.<sup>24</sup> In order to be listed as a PSO, an entity must initially certify to HHS that it has policies and procedures in place necessary for performance of each of eight patient safety activities,<sup>25</sup> and that it will comply with all other relevant criteria once listed as a PSO.<sup>26</sup> The eight patient safety activities a PSO must be able to perform include:

- Efforts to improve patient safety and the quality of health care delivery;<sup>27</sup>
- The collection and analysis of patient safety work product;<sup>28</sup>
- The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;<sup>29</sup>
- The utilization of PSWP for the purposes of encouraging a culture of safety and providing feedback and assistance to effectively minimize patient risk;<sup>30</sup>
- The maintenance of procedures to preserve confidentiality with respect to PSWP;<sup>31</sup>
- The provision of appropriate security measures with respect to PSWP;<sup>32</sup>

---

<sup>21</sup> PSOs will be treated as “business associates,” and patient safety activities of such organizations in relation to a provider will be considered “health care operations of the provider,” for purposes of HIPAA. This relieves providers of an obligation to obtain patient authorization to disclose PSWP containing PHI to PSOs, and requires PSOs to notify the provider of any impermissible use or disclosure of the PHI of which the PSO is aware (PSQIA, 42 U.S.C. § 299B-22(i)).

<sup>22</sup> PSQIA, 42 U.S.C. § 299b-21(8)(A).

<sup>23</sup> 42 CFR § 3.20(A) (page 70734).

<sup>24</sup> PSQIA, 42 U.S.C. § 299b-21(4).

<sup>25</sup> PSQIA, 42 U.S.C. § 299b-24(c)(2)(A) (referring to requirements for certification detailed in § 299b-24(c)(1)(A) (referring to requirements described in § 299b-24(a)(1)(A), (B)); PSQIA, 42 U.S.C. § 299b-24(a)(1)(A).

<sup>26</sup> PSQIA, 42 U.S.C. § 299b-24(a)(1)(B) (listing criteria for entities and component entities).

<sup>27</sup> PSQIA, 42 U.S.C. § 299b-21(5)(A).

<sup>28</sup> PSQIA, 42 U.S.C. § 299b-21(5)(B).

<sup>29</sup> PSQIA, 42 U.S.C. § 299b-21(5)(C).

<sup>30</sup> PSQIA, 42 U.S.C. § 299b-21(5)(D).

<sup>31</sup> PSQIA, 42 U.S.C. § 299b-21(5)(E).

<sup>32</sup> PSQIA, 42 U.S.C. § 299b-21(5)(F).

- The utilization of qualified staff;<sup>33</sup> and
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.<sup>34</sup>

The additional criteria with which a PSO must comply include:

- Its mission and primary activity are to improve patient safety and the quality of health care delivery;<sup>35</sup>
- Has appropriately qualified staff, including licensed or certified medical professionals;<sup>36</sup>
- Has with more than one provider for the purpose of reviewing and receiving PSWP;<sup>37</sup>
- Fully disclose any financial, reporting, or contractual relationship between it and any provider with which it contracts;<sup>38</sup>
- Fully disclose, if applicable, the fact that it is not managed, controlled, and operated independently from any provider with which it contracts;<sup>39</sup>
- To the extent practicable, it collects PSWP from providers in a standardized manner that permits valid comparisons of similar cases among similar providers;<sup>40</sup> and
- It utilizes PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.<sup>41</sup>

Certain entities cannot be PSOs, including health insurance issuers and any affiliated divisions or entities.<sup>42</sup> Components of certain non-qualifying organizations may be certified as a PSO if the component is part of any of the following organizations:<sup>43</sup>

- Provider licensing or accrediting organizations;<sup>44</sup>
- An entity or agent of an entity providing oversight/enforcement of statutory or regulatory requirements governing the delivery of health care services;<sup>45</sup> and
- An entity operating a federal, state, local or tribal patient safety reporting system to which health care providers are required to report information by law or regulation.<sup>46</sup>

<sup>33</sup> PSQIA, 42 U.S.C. § 299b-21(5)(G).

<sup>34</sup> PSQIA, 42 U.S.C. § 299b-21(5)(H).

<sup>35</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(A).

<sup>36</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(B).

<sup>37</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(C).

<sup>38</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(E)(i).

<sup>39</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(E)(ii).

<sup>40</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(F).

<sup>41</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(G).

<sup>42</sup> PSQIA, 42 U.S.C. § 299b-24(b)(1)(D).

<sup>43</sup> 42 CFR § 3.102(a)(2)(iii).

<sup>44</sup> 42 CFR § 3.102(a)(2)(ii)(A).

<sup>45</sup> 42 CFR § 3.102(a)(2)(ii)(B), (C).

<sup>46</sup> 42 CFR § 3.102(a)(2)(ii)(D).

In order to operate as a PSO, components of such organizations must meet all the certification requirements applicable to PSOs as well as satisfy the following requirements:<sup>47</sup>

- Certify that it maintains PSWP separately from the rest of its parent organization, and has established appropriate security measures to maintain the confidentiality of the work product;<sup>48</sup>
- Certify that members of its workforce and any other contractor staff will not make an unauthorized disclosure to the rest of its parent organization in breach of confidentiality;<sup>49</sup>
- Certify that its mission does not create a conflict of interest with the rest of its parent organization;<sup>50</sup> and
- Comply with additional required attestations, information and operational limitations,<sup>51</sup> including not sharing staff with its parent organization,<sup>52</sup> and submitting a statement describing the parent organization's role and the scope of the parent organization's authority with respect to a number of operational activities.<sup>53</sup>

### c.) HOW WILL PSWP BE USED?

Providers and PSOs participating in the program will operate patient safety evaluation systems, which collect, manage and/or analyze information for reporting to or by a PSO.<sup>54</sup> HHS will maintain a network of patient safety databases to serve as an interactive, evidence-based management resource for providers, PSOs and other entities; the network will have the capacity to accept, aggregate across the network, and analyze non-identifiable PSWP voluntarily reported by PSOs, providers, or other entities.<sup>55</sup> Information reported to and among the network of patient safety databases will be used to analyze national and regional statistics, including trends and patterns of health care errors; the information resulting from such analyses will be made available to the public and included in annual quality reports.<sup>56</sup>

---

<sup>47</sup> 42 CFR § 3.102(a)(1)(iii), (iv).

<sup>48</sup> PSQIA, 42 U.S.C. § 299b-24(b)(2)(A).

<sup>49</sup> PSQIA, 42 U.S.C. § 299b-24(b)(2)(B).

<sup>50</sup> PSQIA, 42 U.S.C. § 299b-24(b)(2)(C).

<sup>51</sup> 42 CFR § 3.102(c)(4).

<sup>52</sup> 42 CFR § 3.102(c)(4)(ii)(A).

<sup>53</sup> 42 CFR § 3.102(c)(4)(i)(A).

<sup>54</sup> PSQIA, 42 U.S.C. § 299b-21(6).

<sup>55</sup> PSQIA, 42 U.S.C. § 299b-23(a).

<sup>56</sup> PSQIA, 42 U.S.C. § 299b-23(c). Note: these annual quality reports will be submitted to Congress on national trends in the quality of health care provided to the American people (PSHA, 42 U.S.C. § 299b-2(b)(2)).

## 2.) Protection of Patient Safety Work Product

Identifiable PSWP is subject to privilege and confidentiality requirements, each of which have specific exceptions that permit disclosure under certain circumstances. In order to ensure that disclosure of identifiable PSWP is limited to those circumstances in which it is authorized, a number of enforcement mechanisms are available, including an avenue for individuals to report suspected violations, Secretarial authority to conduct comprehensive compliance reviews, and civil monetary penalties.

### a.) CONFIDENTIALITY, PRIVILEGE AND PROTECTIONS AGAINST DISCLOSURE

PSWP is privileged information, which means it is unavailable for disclosure in the following circumstances, subject to limited exceptions:

- A judicial or administrative court subpoena or order;<sup>57</sup>
- Discovery in connection with a judicial or administrative proceeding against a provider;<sup>58</sup>
- Disclosure under the Freedom of Information Act<sup>59</sup> or any similar Federal, State or local law;<sup>60</sup> and/or
- Admission as evidence in any civil, criminal or administrative proceeding,<sup>61</sup> including a professional disciplinary proceeding.<sup>62</sup>

PSWP is also considered confidential and may not be disclosed, subject to limited exceptions.

In addition to the privilege and confidentiality requirements surrounding PSWP, a PSO cannot be compelled to disclose information it collects or develops, even if the information is not PSWP, unless such information is identified, is not PSWP, and is not reasonably available from another source.<sup>63</sup> PSOs may, of course, be subject to any of the disclosure exceptions applicable to PSWP, as described above.<sup>64</sup> Accrediting bodies may not take accrediting actions against providers who participate in the good faith collection, development, reporting, or maintenance of patient safety work product, and may not require providers to reveal their communications with any PSO.<sup>65</sup> Employers may not take an adverse employment action<sup>66</sup> against an individual based on the following:

<sup>57</sup> PSQIA, 42 U.S.C. § 299b-22(a)(1).

<sup>58</sup> PSQIA, 42 U.S.C. § 299b-22(a)(2).

<sup>59</sup> Please see FOIA section, or go to 5 U.S.C. 552 to access the Act.

<sup>60</sup> PSQIA, 42 U.S.C. § 299b-22(a)(3).

<sup>61</sup> PSQIA, 42 U.S.C. § 299b-22(a)(4).

<sup>62</sup> PSQIA, 42 U.S.C. § 299b-22(a)(5).

<sup>63</sup> PSQIA, 42 U.S.C. § 299b-22(d)(4)(A)(i).

<sup>64</sup> PSQIA, 42 U.S.C. § 299b-22(d)(4)(A)(ii).

<sup>65</sup> PSQIA, 42 U.S.C. § 299b-22(d)(4)(B).

<sup>66</sup> Includes the loss of employment, failure to provide any other employment-related benefit for which the individual would have been eligible (PSQIA, 42 U.S.C. § 299b-22(e)(2)(A)) or an adverse evaluation or decision made



- The individual in good faith reported information to the provider with the intent of having the information reported to a PSO;<sup>67</sup> or
- The individual in good faith reported information directly to a PSO.<sup>68</sup>

Every PSO must comply with standard security requirements at all times and in any location in which the PSO, its workforce members, or its contractors receive, access, or handle PSWP.<sup>69</sup> This requires maintaining policies and procedures that address a number of considerations, including all of the following:

- Properly training workforce and contractors on security protocols and confidentiality measures;<sup>70</sup>
- Distinguishing PSWP from non-PSWP;<sup>71</sup>
- Protecting the media that contains PSWP;<sup>72</sup>
- Employment of physical and environmental protections to control and limit physical and virtual access to places and equipment where PSWP is received, access, or handled;<sup>73</sup>
- Proper identification of those authorized to receive, access or handle PSWP;<sup>74</sup>
- Utilization of an audit to detect inappropriate receipt, access, or handling of PSWP;<sup>75</sup>
- Implementation of methods to prevent unauthorized receipt, access or handling of PSWP;<sup>76</sup> and
- Conducting periodic security assessments to ensure that its security protocols are effective, to correct any identified deficiencies, and to reduce or eliminate any vulnerability.<sup>77</sup>

If an entity's certification as a PSO is revoked, it must notify each provider whose PSWP was collected or analyzed of such revocation within fifteen days.<sup>78</sup> For the first thirty days after removal from the accredited PSO list, any data submitted to the entity will remain protected under the relevant privilege and confidentiality requirements.<sup>79</sup> If the privilege and confidentiality requirements applied to data while the entity was listed (or to data received within thirty days after its removal), those

---

in relation to the accreditation, certification, credentialing, or licensing of the individual (PSQIA, 42 U.S.C. § 299b-22(e)(2)(B)).

<sup>67</sup> PSQIA, 42 U.S.C. § 299b-22(e)(1)(A).

<sup>68</sup> PSQIA, 42 U.S.C. § 299b-22(e)(1)(B).

<sup>69</sup> 42 CFR § 3.106(a).

<sup>70</sup> 42 CFR § 3.106(b)(1)(ii).

<sup>71</sup> 42 CFR § 3.106(b)(2)(i).

<sup>72</sup> 42 CFR § 3.106(b)(2)(ii).

<sup>73</sup> 42 CFR § 3.106(b)(2)(iii).

<sup>74</sup> 42 CFR § 3.106(b)(3)(i).

<sup>75</sup> 42 CFR § 3.106(b)(3)(i).

<sup>76</sup> 42 CFR § 3.106(b)(3)(ii).

<sup>77</sup> 42 CFR § 3.106(b)(4)(i).

<sup>78</sup> PSQIA, 42 U.S.C. § 299b-24(e)(2).

<sup>79</sup> PSQIA, 42 U.S.C. § 299b-24(f)(1).

protections continue to apply after the entity is removed from the listing.<sup>80</sup> A de-accredited entity must comply with the following requirements with respect to any data it receives within thirty days of its removal from the listing:

- The former PSO will transfer such work product or data to another PSO;<sup>81</sup>
- The former PSO will return such work product or data to whatever entity originally submitted it;<sup>82</sup> or
- If returning the product or data to the original submitting entity is not practicable, the former PSO will destroy such work product or data.<sup>83</sup>

## **b.) EXCEPTIONS TO PRIVILEGE AND CONFIDENTIALITY REQUIREMENTS**

The privilege and confidentiality requirements surrounding PSWP are not applicable in certain situations; all PSWP may be disclosed when use of the PSWP falls into any of the following categories:

- For use in a criminal proceeding if a court makes a determination in camera<sup>84</sup> that the PSWP contains evidence of a criminal act, is material to the proceeding and is not reasonably available from any other source;<sup>85</sup>
- To the extent necessary to carry out<sup>86</sup> equitable relief in a civil action brought by any aggrieved individual to redress or enjoin an adverse employment action,<sup>87</sup> if the court or administrative tribunal has issued a protective order to protect the confidentiality of PSWP in the course of the proceeding;<sup>88</sup>
- When authorized by each identified provider<sup>89</sup> via a signed writing that contains enough detail to fairly inform the provider(s) of the nature and scope of the disclosure being authorized;<sup>90</sup>
- Voluntary disclosure of non-identifiable patient safety work product;<sup>91</sup> and/or
- To or by HHS in investigating or determining compliance, imposition of civil money penalties, or making or supporting decisions with respect to listing of a PSO,<sup>92</sup> which may

<sup>80</sup> PSQIA, 42 U.S.C. § 299b-24(f)(2).

<sup>81</sup> PSQIA, 42 U.S.C. § 299b-24(g)(1) Note: both the transferring entity and the new PSO must approve the transfer.

<sup>82</sup> PSQIA, 42 U.S.C. § 299b-24(g)(2).

<sup>83</sup> PSQIA, 42 U.S.C. § 299b-24(g)(3).

<sup>84</sup> In camera means privately in front of a judge; not in open court.

<sup>85</sup> PSQIA, 42 U.S.C. § 299b-22(c)(1)(A).

<sup>86</sup> PSQIA, 42 U.S.C. § 299b-22(c)(1)(B).

<sup>87</sup> PSQIA, 42 U.S.C. § 299b-22(e). Note: States or agencies of state governments may not assert any of the privilege protections described unless before such assertion, the state has consented to be subject to the equitable relief remedies for employers, and such consent has remained in effect.<sup>87</sup>

<sup>88</sup> 42 CFR § 3.206(b)(2).

<sup>89</sup> PSQIA, 42 U.S.C. § 299b-22(c)(1)(C).

<sup>90</sup> 42 CFR § 3.206(b)(3)(i).

<sup>91</sup> PSQIA, 42 U.S.C. § 299b-22(c)(3); PSQIA, 42 U.S.C. § 299b-22(c)(2)(A).

<sup>92</sup> 42 CFR § 3.204(c); 42 CFR § 3.206(d).



be subsequently disclosed by HHS for use by HHS in any of its activities and for use as evidence in any administrative or judicial proceeding.<sup>93</sup>

The following disclosures are exceptions only to the confidentiality requirements applicable to PSWP. They are not available to circumvent the privilege requirements. Disclosure of PSWP may occur in the following circumstances:

- To carry out patient safety activities<sup>94</sup> when such disclosure is between a provider and a PSO,<sup>95</sup> to a contractor of a provider or a PSO,<sup>96</sup> or among affiliated providers;<sup>97</sup>
- To carry out patient safety activities when such disclosure is to another PSO or provider, if thirteen specific identifiers<sup>98</sup> of any providers or affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce or household members of such providers are removed,<sup>99</sup> and direct identifiers<sup>100</sup> in any individually identifiable health information are removed;<sup>101</sup>
- If the PSWP is non-identifiable, whether voluntarily disclosed or not;<sup>102</sup>
- To entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by HHS, for the purpose of conducting research;<sup>103</sup>
- By a provider to the FDA with respect to a product or activity regulated by the FDA;<sup>104</sup>
- Voluntary disclosure by a provider to an accrediting body that accredits that provider;<sup>105</sup>
- For business operations to attorneys, accounts and other professionals,<sup>106</sup> or other business operations prescribed by HHS, if disclosure is consistent with the goals of patient safety improvement;<sup>107</sup>

<sup>93</sup> 42 CFR § 3.312(c)(2).

<sup>94</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(A).

<sup>95</sup> 42 CFR § 3.206(b)(4)(i).

<sup>96</sup> 42 CFR § 3.206(b)(4)(ii).

<sup>97</sup> 42 CFR § 3.206(b)(4)(iii).

<sup>98</sup> Direct identifiers are listed in 42 CFR § 3.206(b)(4)(iv)(A)

<sup>99</sup> 42 CFR § 3.206(b)(4)(iv)(A).

<sup>100</sup> Listed at 45 CFR 164.514(e)(2).

<sup>101</sup> 42 CFR § 3.206(b)(4)(iv)(B).

<sup>102</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(B).

<sup>103</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(C). Note: if work product disclosed for research is by a HIPAA-covered entity (defined at 45 CFR 160.103) and contains HIPAA-defined protected health information (defined at 45 CFR 160.103), disclosure is only permissible to the same extent as it would be permissible under HIPAA (42 CFR § 3.206(b)(6)(ii)).

<sup>104</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(D). Note: any person permitted to receive patient safety work product pursuant to this exception may only further disclose such work product for the purpose of evaluating the quality, safety, or effectiveness of that product or activity to another such person or the disclosing provider (42 CFR § 3.206(b)(7)(ii)).

<sup>105</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(E). Note: an accrediting body may not further disclose patient safety work product it receives pursuant to this exception (42 CFR § 3.206(b)(8)(ii)), and may not take an accrediting action against a provider based on good faith participation of the provider in the collection, development, reporting or maintenance of patient safety work product in accordance with these rules nor require a provider to reveal its communications with any PSO (42 CFR § 3.206(b)(8)(iii)).

- To law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime), if the person making the disclosure reasonably believes, under the circumstances, that the disclosure is necessary for criminal law enforcement purposes;<sup>108</sup>
- The disclosure does not include materials that assess the quality of care of an identifiable provider,<sup>109</sup> or do not include materials that describe or pertain to one or more actions or failures to act by an identifiable provider,<sup>110</sup> if the entity or individual making the disclosure is not a PSO.<sup>111</sup>

In addition to these disclosure exceptions, a component PSO may provide individuals in or units of its parent organization with access to identifiable PSWP in the following situation:

- There is an agreement that access to such work product will be limited to what is necessary to assist the component in the conduct of patient safety activities;<sup>112</sup> and
- Those given access will not use or disclose such information beyond what is required to assist the component PSO, will take appropriate security measures to prevent unauthorized disclosures, and will comply with the general certifications the component PSO made regarding unauthorized disclosures.<sup>113</sup>

If any PSWP is disclosed via an authorized exception, the PSWP will continue to be confidential and privileged after such disclosure, and the confidentiality and privilege requirements will apply in equal measure to the person to whom the information was disclosed.<sup>114</sup> However, if the PSWP is disclosed in accordance with the exception provided for criminal proceedings, the confidentiality protection will no longer apply to the PSWP.<sup>115</sup> Additionally, if the PSWP disclosed is non-identifiable, neither the privilege nor the confidentiality protections will continue to apply to the non-identifiable PSWP.<sup>116</sup>

---

<sup>106</sup> 42 CFR § 3.206(b)(9)(i). Note: such contractors may not further disclose patient safety work product except to the entity from which they received the information.

<sup>107</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(F).

<sup>108</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(G). Note: law enforcement personnel receiving work product pursuant to this exception may only disclose such work product to other law enforcement authorities as needed for law enforcement activities related to the event that gave rise to the initial disclosure (42 CFR § 3.206(b)(10)(ii)).

<sup>109</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(H)(i).

<sup>110</sup> PSQIA, 42 U.S.C. § 299b-22(c)(2)(H)(ii).

<sup>111</sup> Note: this is referred to the “safe harbor” provision in the implementing regulations (42 CFR § 3.206(c)).

<sup>112</sup> 42 CFR § 3.102(c)(3)(i).

<sup>113</sup> 42 CFR § 3.102(c)(3)(ii).

<sup>114</sup> PSQIA, 42 U.S.C. § 299b-22(d)(1).

<sup>115</sup> PSQIA, 42 U.S.C. § 299b-22(d)(2)(A).

<sup>116</sup> PSQIA, 42 U.S.C. § 299b-22(d)(2)(B).

### c.) ENFORCEMENT PROVISIONS

**Reporting Confidentiality Violations:** Any person who believes that patient safety work product has been disclosed in violation of the confidentiality provisions may file a complaint with HHS.<sup>117</sup> Such complaint must be in writing,<sup>118</sup> name the subject of the complaint and describe the acts believed to be in violation of the confidentiality provisions.<sup>119</sup>

**Compliance Reviews:** HHS may assess or verify any PSO's compliance with requirements by requesting information or conducting reviews of, or site visits to, PSOs.<sup>120</sup> HHS may inspect the physical or virtual sites maintained or controlled by the PSO, and may inspect or obtain copies of any necessary PSO records, including PSWP.<sup>121</sup> Respondents must keep records and submit compliance reports as required by HHS,<sup>122</sup> must cooperate with complaint investigations and compliance reviews,<sup>123</sup> and must permit HHS access to any sources of information that are pertinent to ascertaining compliance with the confidentiality provisions.<sup>124</sup>

**Confidentiality Violations:** The Office for Civil Rights will investigate and enforce compliance with the confidentiality provisions.<sup>125</sup> A person who knowingly or recklessly discloses identifiable PSWP in violation of the confidentiality requirements<sup>126</sup> will be subject to a civil monetary penalty<sup>127</sup> of up to \$10,000 for each violation,<sup>128</sup> as will any principal based on the act of his agent, in accordance with the federal common law of agency.<sup>129</sup> In determining the amount of the penalty,<sup>130</sup> HHS may consider aggravating or mitigating factors as appropriate.<sup>131</sup> When a penalty is final, HHS will notify the following of the penalty and the reason it was imposed:<sup>132</sup>

- The public;

---

<sup>117</sup> 42 CFR § 3.306(a).

<sup>118</sup> 42 CFR § 3.306(b)(1).

<sup>119</sup> 42 CFR § 3.306(b)(2).

<sup>120</sup> 42 CFR § 3.308.

<sup>121</sup> 42 CFR § 3.110.

<sup>122</sup> 42 CFR § 3.310(a).

<sup>123</sup> 42 CFR § 3.310(b).

<sup>124</sup> 42 CFR § 3.310(c)(1). Note: HHS must be granted such access during normal business hours; if HHS determines that exigent circumstances exist, access must be granted at any time and without notice. If the information required is exclusively in the possession of another entity, and the other entity fails or refuses to furnish the information, the respondent must so certify and set forth what efforts it has made to obtain the information (42 CFR § 3.310(c)(2)).

<sup>125</sup> 42 CFR Part 3 (page 70732)

<sup>126</sup> Note: Penalties may not be imposed under both the PSQIA and HIPAA for a single act or omission (42 U.S.C. § 299b-22(f)(3)).

<sup>127</sup> Civil monetary penalties under the PSQIA will be applied in accordance with the provisions of Title 11 of the Social Security Act, § 1128A (Available at 42 U.S.C. § 1320a-7a), starting from the second sentence of § 1128A(c)(1).

<sup>128</sup> PSQIA, 42 U.S.C. § 299b-22(f)(1).

<sup>129</sup> 42 CFR § 3.402(b).

<sup>130</sup> 42 CFR § 3.408.

<sup>131</sup> 42 CFR § 3.408.

<sup>132</sup> 42 CFR § 3.426.

- The appropriate state or local medical or professional organization;
- State agenc(ies) administering or supervising the administration of state health care programs;
- The appropriate utilization and quality control peer review organization; and
- The appropriate state or local licensing agency or organization of the penalty.

**ALJ Hearings:** A respondent is permitted to request a hearing before an ALJ;<sup>133</sup> if such request is granted, the hearing must conform to a number of adjudicatory requirements.<sup>134</sup> The record of such hearing must be recorded and transcribed, and may be obtained following the hearing;<sup>135</sup> the record of the decision, including the transcript of the testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding,<sup>136</sup> may be inspected and copied by any person, unless otherwise ordered by the ALJ for good cause shown.<sup>137</sup>

---

<sup>133</sup> 42 CFR § 3.504(a).

<sup>134</sup> 42 CFR § 3.504, et. seq.

<sup>135</sup> 42 CFR § 3.542(a).

<sup>136</sup> 42 CFR § 3.542(b).

<sup>137</sup> 42 CFR § 3.542(c). Note: good cause may include the presence in the record of identifiable patient safety work product.