RULES AND REGULATIONS

Title 55—HUMAN SERVICES

DEPARTMENT OF HUMAN SERVICES

[55 PA. CODE CHS. 51, 2380, 2390, 6100, 6200, 6400 AND 6500]

Home and Community-Based Services and Licensing

[49 Pa.B. 5777]
[Saturday, October 5, 2019]

The Department of Human Services (Department), by this order, adopts the regulations set forth in Annex A under the authority of sections 201(2), 403(b), 403.1(a) and (b), 911 and 1021 of the Human Services Code (62 P.S. §§ 201(2), 403(b), 403.1(a) and (b), 911 and 1021) and section 201(2) of the Mental Health and Intellectual Disability Act of 1966 (50 P.S. § 4201(2)). Notice of proposed rulemaking was published at 46 Pa.B. 7061 (November 5, 2016). Advance notice of final rulemaking regarding § 6100.571 (relating to fee schedule rates) was published at 47 Pa.B. 4831 (August 19, 2017).

Purpose of Final-Form Rulemaking

The purpose of this final-form rulemaking is to support individuals with an intellectual disability or autism to live and participate in the life of their community, to achieve greater independence and to have opportunities enjoyed by all citizens of this Commonwealth. This final-form rulemaking strengthens community services and supports to promote person-centered approaches, community integration, personal choice, quality in service delivery, health and safety protections, competitive integrated employment, accountability in the utilization of resources and innovation in service design.

This final-form rulemaking governs the program, operational and fiscal aspects of the following: (a) home and community-based services (HCBS) provided through the 1915(c) waiver programs; (b) Medicaid State plan HCBS for individuals with an intellectual disability or autism, including targeted support management; and (c) services funded exclusively by grants to counties under the Mental Health and Intellectual Disability Act of 1966 (50 P.S. §§ 4101—4704) or Article XIV-B of the Human Services Code (62 P.S. §§ 1401-B—1410-B), commonly referred to as "base-funding." This final-form rulemaking amends the licensing regulations in Chapters 2380, 2390, 6400 and 6500 to make them compatible with Chapter 6100 (relating to services for individuals with an intellectual disability or autism) in the areas of training, rights, individual planning, incident management, restrictive procedures and medication administration. The licensing regulations encompass health, safety and well-being protections for individuals with a disability or autism who receive services in a licensed adult training facility, vocational facility, community home or life sharing home. This final-form rulemaking rescinds and replaces Chapters 51 and 6200 with Chapter 6100.

This final-form rulemaking is needed to continue the Commonwealth's eligibility for Federal financial participation in the HCBS waiver programs. See 42 CFR Part 441, Subpart G (relating to home and community-based services: waiver requirements). This final-form rulemaking protects the health, safety and well-being of the individuals receiving services in individual-directed, family-based, community residential and day programs funded through the Federal waivers, the Commonwealth's Title XIX State plan and base-funding, as well as individuals who receive services in community residential and day programs funded through private pay or another funding source.

Background

The Office of Developmental Programs (ODP) currently administers four 1915(c) "waivers." The term "waiver" in this context refers to administering a program under the authority of section 1915(c) of the Social Security Act (42 U.S.C.A. § 1396n(c)) that permits a state to waive Medicaid requirements on comparability, statewideness and income and resource rules in order to furnish an array of HCBS that promote community living and avoid institutionalization. Waiver services complement and supplement services available through the Medicaid State plan and other Federal, state and local public programs, as well as the supports that families and communities provide to individuals.

States have flexibility in designing waivers, including the options to determine the target groups of Medicaid beneficiaries who receive services through each waiver; specify the services to support waiver participants in the community; allow participants to self-direct services; determine qualifications of waiver providers; design strategies to assure the health and well-being of waiver participants; manage a waiver to promote the cost-effective delivery of HCBS; and, develop and implement a quality improvement strategy.

States submit a waiver application to the Federal Centers for Medicare and Medicaid Services (CMS) to operate a 1915(c) waiver program. After initial approval of a waiver application by CMS, each waiver must be renewed every 5 years. Changes to provisions in the waivers may be submitted with a waiver renewal application or at any time through a waiver amendment process. Initial waiver applications, waiver renewal applications and amendments that contain substantive changes must follow the public comment process as outlined in the CMS guidance, found at Application for a § 1915(c) Home and Community-Based Waiver, Instructions, Technical Guide and Review Criteria, § 6-I: Public Input.

Services in the waivers must be provided by Medicaid providers that meet the qualification standards outlined in the waiver application. Each provider of waiver services must also sign a Medicaid provider agreement prior to furnishing services under the waiver. See 42 CFR 431.107 (relating to required provider agreement).

Affected Individuals and Organizations

Chapter 6100 applies to a broad scope of programs receiving Commonwealth and Federal funds. This final-form rulemaking applies to 1,060 HCBS and base-funding service provider agencies providing services to more than 53,000 individuals with an intellectual disability or autism. Chapter 6100 applies to the ODP service system, including those facility-based services that are licensed and funded by the Department under Chapters 2380, 2390, 6400 and 6500, as well as many services that are funded, but that do not require licensure under Articles IX and X of the Human Services Code (62 P.S. §§ 901—922 and 1001—1088). See sections 201(2), 403(b), 403.1(a) and (b), 911 and 1021 of the Human Services Code (62 P.S. §§ 201(2), 403(b), 403.1(a) and (b), 911 and 1021).

Chapter 2380 (relating to adult training facilities) contains licensing regulations to protect the health, safety and well-being of adults served in this Commonwealth's 416 licensed adult day training facilities with a maximum Statewide licensed capacity of 26,429 individuals. Chapter 2380 contains the minimum requirements that apply regardless of the payment agency. For instance,

Chapter 2380 applies to a facility that provides services exclusively to individuals with blindness, deafness or a mental illness, including those facilities that are not funded by the Department through the ODP service system. Services for some individuals, and services provided by some facilities, are funded exclusively through private insurance, private-pay or out-of-State sources. Providers funded by the Department through the ODP waiver programs must enroll in the Medical Assistance Program, sign a Medical Assistance provider agreement and sign an ODP waiver provider agreement. The number of licensed adult day training facilities in which there is no ODP waiver provider agreement is 15.

Chapter 2390 (relating to vocational facilities) contains licensing regulations to protect the health, safety and well-being of adults served in this Commonwealth's 166 licensed vocational facilities with a maximum Statewide licensed capacity of 21,754 individuals. Chapter 2390 contains the minimum requirements that apply regardless of the payment agency. For instance, Chapter 2390 applies to a facility that provides services exclusively to individuals with blindness, deafness or a mental illness, including those facilities that are not funded by the Department through the ODP service system. Services for some individuals, and services provided by some facilities, are funded exclusively through private insurance, private-pay or out-of-State sources. The number of licensed vocational facilities in which there is no ODP waiver provider agreement is nine.

Chapter 6400 (relating to community homes for individuals with an intellectual disability or autism) contains licensing regulations to protect the health, safety and well-being of children and adults served in this Commonwealth's 5,413 licensed community homes for individuals with an intellectual disability or autism with a maximum Statewide licensed capacity of 18,713 individuals. Chapter 6400 contains the minimum requirements that apply regardless of the payment agency. For instance, Chapter 6400 applies to a facility that provides services exclusively to individuals who are not funded by the Department through the ODP service system. Services for some individuals, and services provided by some facilities, are funded exclusively through private insurance, private-pay or out-of-State sources. The number of licensed community homes in which there is no ODP waiver provider agreement is 113.

Chapter 6500 (relating to life sharing homes) contains licensing regulations to protect the health, safety and well-being of children and adults served in this Commonwealth's 1,583 licensed life sharing homes for individuals with an intellectual disability or autism with a maximum Statewide licensed capacity of 2,504 individuals. Chapter 6500 contains the minimum requirements that apply regardless of the payment agency. There are fewer than ten privately-funded licensed life sharing homes.

These five chapters govern providers of the services covered under Chapter 6100 and providers licensed under Chapters 2380, 2390, 6400 and 6500; however, other interested and affected parties include the individuals who receive services; the families and friends of the individuals who receive services; advocates who provide support and representation for the individuals to assure that their rights are protected; county governments that provide authorization for the use of base-funding under Chapter 6100; and the designated managing entities, which are often county governments that are delegated certain functions by the Department to oversee the provision of the HCBS.

Accomplishments and Benefits

This final-form rulemaking strengthens community services by promoting person-centered approaches, community integration, personal choice, quality in service delivery, health and safety protections, competitive integrated employment, accountability in the utilization of resources and innovation in service design.

Benefits for individuals, families and advocates include strengthened individual rights and service involvement; strict involuntary discharge conditions and procedures; the prohibition of restraints except for the emergency use of a protective physical hold; a team, including a behavior specialist,

to approve the use of a restrictive procedure prior to use; strengthened health and safety protections; equitable program and operational standards for programs serving individuals with an intellectual disability or autism; and the administration of medication by trained staff persons.

Benefits for providers include the reduced administrative burden by coordinating multiple chapters of departmental regulations; the inclusion of autism programs in the core standards to alleviate the administrative burden of managing dual processes; the significant reduction in the conflict of interest protocol requirements; the change in the reserved capacity provision to provide increased reimbursement through modified fee schedule rates to support the return of an individual after extended medical, hospital or therapeutic leave; clarity of the documentation required to support a claim for payment; implementation of a 3-year update of the data used to establish the fee schedule rates; the delineation of specific factors to be examined and used to develop the fee schedule rates; elimination of the requirement to report and deduct donations; and significant reduction and simplification of the cost-based payment requirements.

Benefits for county intellectual disability and autism programs include clarity and compatibility of roles for the support coordinators, base-funding support coordinators and targeted support managers; deletion of conflicting individual plan time frames between the Federal waivers and the multiple chapters of regulations; acknowledgement of the county human rights committees; and the strengthened regulation of exclusively base-funding services. This final-form rulemaking provides consistent program and operational requirements across the ODP service system on a Statewide basis to support the ease of individual transitions from county to county, as well as individual transitions across the various funding sources. This final-form rulemaking eases individual transitions from services funded through base-funding only to HCBS Federal funding.

Additional benefits of the regulation include compliance with the Federal requirements to support continued Federal HCBS funding; the reduced volume of regulations with improved coordination efforts across multiple chapters of regulations providing an opportunity for streamlined compliance monitoring; consistent program requirements and health and safety protections for the individuals across multiple funding sources; the alignment of intellectual disability and autism standards to the benefit of both programs; and the establishment of a baseline of core values across multiple programs.

Fiscal Impact

The provider's regulatory compliance management and associated self-monitoring costs will be reduced. By simplifying and shortening the length of this final-form rulemaking, and by coordinating the program and operational requirements across multiple chapters of licensing regulations as well as across multiple funding streams, the complexity of regulatory compliance management is significantly simplified. The reduced cost impact for a provider will vary based on the pay scale and number of management positions devoted to regulatory compliance management.

Some new costs will be associated with the regulation regarding background checks since a wider net has been cast as to who shall submit a background check. This provision is strongly supported by many individuals and advocates. It is also required under recent amendments to the Child Protective Services Law. In this final-form rulemaking, all persons who provide services that are funded by the Department through the ODP service system must submit a background check to identify any history of abuse, assault, theft or other crimes that may impact the well-being of an individual receiving services. The fee for a Pennsylvania State Police background check is $8. The fee for a Pennsylvania child abuse check is $8, which is rarely required since approximately 87% of the individuals who receive services under Chapter 6100 are adults. The fee for a Federal Bureau of Investigation (FBI) check is $25.75, which includes fingerprinting.

For a person who will provide services to adults, the Older Adults Protective Services Act (35 P.S. §§ 10225.101—10225.5102) requires an FBI check only if the person lived outside of this

Commonwealth within the past 2 years. See 35 P.S. § 10225.502(a)(2). Under 23 Pa.C.S. §§ 6301—6386 (relating to Child Protective Services Law) an FBI check for all paid staff who provide services to children is required. See 23 Pa.C.S. § 6344(b)(3) (relating to employees having contact with children; adoptive and foster parents). The Child Protective Services Law also requires an FBI check for volunteers who have lived outside of this Commonwealth within the previous 10 years. See 23 Pa.C.S. § 6344.2 (relating to volunteers having contact with children). The impact of this requirement is limited, however, since only 13% of the individuals covered by this final-form rulemaking are children. The cost of the background check for the majority of prospective staff persons is $8. The cost of the background check may be borne by the job applicant or by the provider agency. The overall cost impact relating to background checks will vary, as some providers already require background checks on all persons, thus negating or minimizing the cost impact. The increased background check costs are factored into the new HCBS rates.

Significant additional revenue to the providers will result immediately from the revised § 6100.55 (relating to reserved capacity) that changes the providers' approved program capacity to allow for an increase in the providers' rates for the time period of an individual's extended absence because of medical, hospital or therapeutic leave.

Some new costs will be associated with this final-form rulemaking regarding staff training since more staff persons must receive training in areas such as rights, abuse prevention and incident reporting. It is critical that all persons who provide services, including ancillary services, have the minimum training necessary to identify and know what to do if they observe abuse, an incident or a violation of rights. The Department has developed and will offer online training courses free of charge related to the required core training topics, such as individual rights protections, abuse prevention and incident reporting. While use of the Departmental online training courses is optional, these courses meet the requirements of this final-form rulemaking, while saving training development costs for providers. Annual training can be provided on the job as part of the staff person's scheduled work day, through supervisory conferences, staff meetings or training provided for individuals and staff persons at the same time. For an ancillary position, an average of 1 hour of training must be provided each month, which can be provided on the job. For instance, an administrative staff person may complete an online course on the agency's new word processing software; a fiscal staff person may complete an online course on the agency's required accounting methods; a maintenance staff person may be taught the Federal Occupational Safety and Health Administration (OSHA) rules for safe use of a new lawn care machine by a supervisor; or a dietary staff person may watch and learn new cooking techniques or recipes from a televised cooking show. Many providers will experience no increase in training costs as they already provide incident management, abuse reporting and other value-based training to all staff, including ancillary staff; however, for those providers who do not currently train ancillary staff, the fee schedule rates provide sufficient HCBS reimbursement for the training of all staff positions.

Cost savings related to staff training in § 6100.143 (relating to annual training) will be realized over the course of the first year of implementation of this final-form rulemaking with the reduction of the number of training hours from 40 hours to 24 hours for support coordinators and from 24 to 12 hours for chief executive officers.

A requirement that the human rights team include a professional who has a recognized degree, certification or license relating to behavior support who did not develop the behavior support component of the plan is added to this final-form rulemaking as suggested by public comment. See §§ 2380.154, 2390.174, 6100.344, 6400.194 and 6500.164. The qualifications of the behavior specialist are intentionally broad to permit an array of professionals to serve in this capacity. Many providers already employ or contract with a behavior specialist to provide consultation to develop and review individual plans for individuals for whom a restrictive procedure is appropriate. If the provider does not have a behavior specialist on staff or under contract, the provider may utilize a county mental health, intellectual disability and autism program human rights team (county team) or

coordinate with other providers to share this position. If the provider has a behavior specialist or if a county team is used, there will be no new costs to implement this section. For a provider that provides services to multiple individuals for whom restrictive procedures are used and that employs or contracts directly with a behavior specialist to meet this requirement, the annual program-wide cost is estimated at $6,048, based on an hourly rate of $84, meeting twice monthly for 3 hours per meeting, during all 12 months of a year.

A requirement is added for a behavior specialist to develop the behavior support component of an individual plan if a physical restraint will be used or if a restrictive procedure will be used to modify an individual's rights. See §§ 2380.155(d), 2390.175(d), 6100.345(d), 6400.195(d) and 6500.165(d). The estimated cost for a behavior specialist to develop the behavior support component of an individual plan is $1,680 per individual, based on an hourly rate of $84, and providing an average of 20 hours of observation and consultation necessary to design the initial individual plan. The increased behavior specialist consultation costs are factored into the new HCBS rates.

Cost savings will result from the development of a new modified medication administration training course in § 6100.468(d) (relating to medication administration training) for those providers who have been providing the full medication administration training course for all life sharers and others who will now be eligible for the shortened, modified course. This cost reduction will be realized over the course of the first year of implementation of the new regulation. Numerous life sharing provider agencies already require completion of the full medication administration training course by their life sharers, so completion of the new modified training course will be a cost reduction. The cost of the certified train-the-trainer program is paid by the Department for a certified medication administration trainer who assists the life sharer through the modified medication administration training course. For those life sharing provider agencies who do not currently complete the medication administration training course, a slight cost increase will result; however, the cost will be minimal as the new modified training course will take only several hours to complete online and the cost is factored into the new HCBS rates.

Beginning in January 2018, the current cost-based system for residential HCBS converted to a fee schedule rate, resulting in significant cost-savings for the providers and reduced administration costs for the Department. The fee schedule rates were determined based upon the cost to deliver each service and based upon the factors addressed in § 6100.571(b) (relating to fee schedule rates). The provider will realize an administrative cost savings since the provider is no longer required to complete and submit detailed cost reports; nor do providers need to track and monitor cost-based regulatory compliance data. The requirements contained in current §§ 51.71—51.103 and in new §§ 6100.641—6100.672 no longer apply for residential services, since the payment methodology transitioned to a fee schedule rate in January 2018. The Department will realize a cost savings through the reduction of the administrative review and approval of cost reports.

The reporting of donation section formerly in § 51.82 is deleted. This results in additional revenue to the provider, because the provider no longer has to declare and deduct donations from the cost reports.

Paperwork Requirements

Decreased paperwork will result from the reduction of the provider's regulatory compliance efforts due to the coordination of multiple chapters of regulations and the reduction in the number of regulations. An opportunity is provided for the Department and the county programs to better coordinate and reduce duplicative monitoring efforts between licensing and waiver compliance management; this monitoring reduction will reduce paperwork for the provider, the county program, the designated managing entity and the Department.

Decreased provider paperwork will result from the elimination of the specific requirements regarding the content of the conflict of interest policy in § 6100.53 (relating to conflict of interest). In the current § 51.33, there are detailed requirements regarding five areas governing an internal conflict of interest protocol and disclosure to the Department. This final-form rulemaking requires only that the provider develop and implement a policy. There are no longer any requirements as to the content of the policy or submission to the Department.

Quality management plans and the quality management monitoring cycle is extended from the current 2-year cycle to a 3-year cycle, reducing paperwork requirements.

Increased paperwork for the provider may result from the expansion of the scope of the persons for which background checks and training is required. Many providers already require and track background checks and training across a larger segment of employees than was previously required, thus minimizing the paperwork increase for many providers. In addition, better protections for the individuals who receive services outweigh any increase in paperwork related to the background checks and training.

The individual plan in § 6100.223 (relating to content of the individual plan) is significantly simplified and the process is streamlined, thus reducing paperwork.

Decreased provider paperwork will result from the elimination of duplicate and conflicting incident reporting requirements for licensing and waiver compliance. In § 6100.401 (relating to types of incidents and timelines for reporting), incident reports for emergency room visits and non-prescribed over-the-counter medication errors are no longer required, reducing the number of incidents to be reported. Also eliminated is the provider paperwork required by the licensing regulations to maintain a record of incidents that are not reportable, such as minor illnesses. While many providers will choose to retain this documentation as best practice, the Department will no longer review this documentation for regulatory compliance.

The reporting of donation section formerly at § 51.82 is deleted. This results in a reduction of paperwork for the provider, as well as additional revenue to providers, because a provider does not have to declare and deduct donations from the cost reports.

In § 6100.686 (relating to room and board rate), the paperwork required to complete the proration of the board costs is reduced from the current daily proration requirement in § 51.121(d)(2) to a consecutive period of 8 or more days in this final-form rulemaking. This regulation change will result in reduced paperwork for the provider.

Public Comment

A total of 345 public comments were received in response to the proposed rulemaking. Of those 345 comments, approximately 200 were unique comments, while approximately 145 were either full or partial duplicates from the same agency or another organization. The comments received represented the following individuals or groups: 2 individuals; 13 families; 4 legislators; 6 advocates; 4 universities; 8 county governments; 4 provider associations; 291 providers; with the remaining comments received from other or unidentified sources. These numbers are estimates as some commentators represent more than one constituency group.

A total of 90 public comments were received in response to the advance notice of final rulemaking. Of those 90 comments, approximately 36 were unique comments, while approximately 54 were duplicates from the same agency or another organization. The comments on the advance notice of final rulemaking represented the following individuals or groups: 7 families; 3 advocates; 4 provider associations; 69 providers; with the remaining 7 comments received from other or unidentified sources.

The Department has continuously supported, encouraged and managed an active and open community participation process throughout the development of the proposed rulemaking and this final-form rulemaking. The Department values, commends and greatly appreciates the expertise, time and attention contributed by the public commentators, and in particular the regulation work group (work group) comprised of 45 persons representing a broad range of interests, experiences and ideas, including individuals, families, advocates, universities, county programs, providers and provider organizations. The work group met for 13 days over a 3-year period to advise the Department of its collective and individual concerns and suggestions, cultivate constructive dialogue and promote an understanding of the views of others.

Following the close of the proposed rulemaking public comment period, a 3-day meeting of the work group was convened to discuss the public comments relating to the 20 regulatory areas that were of most concern to the public commentators. In many sections of the final-form regulation, a diversity of opinions continues to be evident; however, for several regulatory areas, including consistency across the four licensing chapters and Chapter 6100, children's services and quality management, reasonable agreement was reached.

On October 18, 2017, a work group meeting was held to review 11 specific portions of the final-form regulation and discuss implementation planning with the external stakeholders.

The advice of the work group and the public comments received in response to the proposed rulemaking and the advance notice of final rulemaking were thoroughly analyzed and considered as the Department prepared the final-form regulation.

During the course of the development of the final-form regulation, more than 40 meetings were held with Statewide and regional self-advocacy, advocacy, family, provider and county organizations to review and discuss specific areas of the regulation. These discussions focused on the constituent issues that are important to the affected parties. The Department values the constructive advice and the unique perspectives provided during these meetings and the final-form regulation encompasses these views.

Discussion of Comments and Major Changes

Following is a summary of the substantive comments received within the public comment period following publication of the proposed rulemaking, substantive comments received in response to the advance notice of final rulemaking and the Department's response to those comments. A summary of the major changes from proposed rulemaking is included. In addition to the major changes listed, the Department made changes in the preparation of the final-form regulation, including correcting typographical errors, reformatting to enhance readability and revising language to enhance clarity and conform to the changes made in response to comments. If a comment was received addressing both Chapter 6100 and one or more of the four licensing chapters, it is recorded under Chapter 6100; however, the applicable sections in all five chapters are listed in the following comment and response discussion.

General—Cross-system regulatory approach

More than 50 commentators, plus numerous form letters from commentators representing families, advocates, county government, universities and providers, commend the Department for aligning the four chapters of licensing regulations and the chapter of program, operational and payment regulations to remove the conflicts and inconsistences across the service system. The commentators ask the Department to maintain this consistency across all five chapters as changes are made to the final-form regulation. The Independent Regulatory Review Commission (IRRC) and numerous providers recognize and appreciate the extensive effort of the Department to align and amend the five chapters of regulations simultaneously.

A few commentators support consistency across the five chapters, but request that the four licensing chapters be combined and collapsed into Chapter 6100.

Response

Four existing chapters of licensing regulations govern many of the same facilities that are also funded through the Federal waivers, the Commonwealth's Title XIX State plan and base-funding allocations. To provide consistency among the HCBS provisions and the four licensing chapters, the final-form regulation includes revisions to the four licensing chapters to promulgate corresponding requirements for six major program and operational areas, including staff training, rights, incident management, individual plans, restrictive procedures and medication administration. As requested, the Department made corresponding changes from proposed rulemaking to the final-form regulation across all five chapters.

The Department appreciates the support of the regulated community and other affected parties to align the five chapters of regulations. While this was a massive undertaking, this alignment will reduce compliance management efforts at the provider, county and State levels. The time saved in the coordination of regulatory management functions will permit all levels of the service system to focus on improving the quality of services to the individuals.

Five chapters must be maintained as the statutory authority for the four licensing chapters differs from the statutory authority for Chapter 6100. While there is some overlap of the applicability of the five chapters, there is not a complete overlap. Each chapter must stand alone to address the variant statutory authority, purpose and scope of the chapters. The Affected Individuals and Organizations section of this preamble explains the differences in the applicability of Chapter 6100 and the four licensing chapters.

General—Consistency of terms and provisions across the five chapters

The IRRC and several commentators note that while consistency across all five chapters is supported, some terminology differs and not all sections are identical in format or language across the five chapters. In particular, the IRRC asks why § 6100.404 (relating to final incident report) is not mirrored in the four licensing chapters.

Response

Some differences in terminology between the four licensing chapters and Chapter 6100 are necessary because of the different approaches to the comprehensiveness of the amendments to the final-form regulation. Chapter 6100 is a new chapter; there is no existing language or format restriction for a new regulatory chapter; however, the amendments to Chapters 2380, 2390, 6400 and 6500 amend only the portions of those chapters relating to staff training, individual rights, incident management, individual plans, restrictive procedures and medication administration. The majority of the requirements in the four licensing chapters are not proposed for amendment. Therefore, the changes to the four licensing chapters must be folded into the existing regulatory format, adapting to language used in the existing chapters.

In response to the specific example provided by the IRRC, the final incident report requirement in § 6100.404 is carried over into the four licensing chapters. See final-form regulation §§ 2380.17(i)-(j), 2390.18(i)-(j), 6400.18(i)-(j) and 6500.20(i)-(j). This is an example of how the amendments in the licensing chapters must conform to the existing format of the four licensing chapters. In Chapter 6100, a separate stand-alone section, § 6100.404, is included to address the final incident report; however, due to existing formatting constraints, the licensing chapters include these requirements as subsections (i) and (j) under a broad incident report and investigation section.

In the example that the IRRC provides, the term "provider" is used in § 6100.404 consistent with its use throughout Chapter 6100; however, § 2380.17 (relating to incident report and investigation) uses the term "facility" since the term "facility" is necessary to maintain compatibility with the language used throughout Chapter 2380. Because Chapter 2380 is not being revised in its entirety, the amended terminology must be consistent with the terms used in the existing Chapter 2380.

In some cases, the Department intentionally does not carry the requirements of Chapter 6100 over to the four licensing chapters if the requirements relate only to those services that the Department funds through the ODP service system. The Affected Individuals and Organizations section of this preamble explains the differences in the applicability of Chapter 6100 and the four licensing chapters. For example, § 6100.226 (relating to documentation of claims) is an important section detailing how to document a claim for purposes of reimbursement; however, since some licensed facilities are not funded by the Department through the ODP service system, this section does not apply for purposes of licensing.

In other cases, the final-form regulation intentionally excludes or changes certain Chapter 6100 requirements from the licensing chapters in an attempt to distinguish the requirements for an ODP service system funded by the Department and one that receives no such funding. In preparing the final-form regulation, the differences were carefully reviewed, and where possible and appropriate, the final-form regulation aligns the five chapters. In the example relating to § 6100.404, the licensing regulations include the option of submitting an incident on a paper form, rather than through the Department's online information management system because some licensed facilities do not have access to the ODP online incident reporting system. This difference remains. See the comments and responses for each individual section further explaining the differences and similarities of the five chapters.

General—Achievement of consensus

The IRRC commends the Department for convening numerous meetings with various stakeholders; however, the IRRC questions why consensus among the stakeholders was not reached. The IRRC asks the Department to attempt to strike the appropriate balance of protecting the public health, safety and well-being while addressing the concerns of the regulated community.

Response

The Department agrees with the IRRC that the role of an effective regulator is always to strike the balance of the needs, concerns, benefits and risks of the affected stakeholders. This regulation is no different. While at the surface there may seem to be overwhelming discourse among the stakeholders, at the heart of the discussion are the core shared vision and strongly held values to provide the highest quality service to the individual.

The regulatory development process was open and inclusive, providing commentators with multiple opportunities over a 3-year period to express their opinions based on their own experiences and frames of reference. The experiences and priorities of an individual who has an intellectual disability or autism and who lives in a community home are inherently different from the provider that provides services to the individual, or from the county program that is responsible for the oversight of a large number of diverse providers and individuals with specific needs and preferences. The Department views these professional, personal and practical differences in perspective, and the opportunities for stakeholders to continuously discuss policies, practices and operations, as the most vibrant asset of the ODP service system. While full consensus is not reached on numerous topics, including staff training, background checks, rights, restrictive procedures and payment methodologies, the rich discussion and diverse perspectives shared openly by persons and groups helped to advise the Department in its deliberation and decision-making process.

The Department believes that the final-form regulation strikes an appropriate balance between protecting the health, safety and well-being of the individuals who receive services, with fair and deliberate consideration given to the administrative and economic impact on the regulated community.

General—Compliance with applicable statutes and regulations

A provider and a university request that compliance with the Americans with Disabilities Act (ADA) be mandated in the regulation. A commentator asks to explain what is included in § 2390.24 (relating to applicable statutes and regulations).

Response

The Department appreciates this comment and supports rigorous and continuous compliance with the ADA. See Americans with Disabilities Act, Pub.L. No. 101-336, as amended, 42 U.S.C.A. §§ 12101—12213. Compliance with the ADA, as well as all applicable Federal, State and local statutes, regulations and ordinances is required across all five chapters. To emphasize that all laws must be followed, and in keeping with the recommendation to align all five chapters, the Department added § 6100.52 (relating to applicable statutes and regulations) to reference compliance with other applicable statutes, regulations and ordinances as proposed in §§ 2380.26, 2390.24, 6400.24 and 6500.25. Other applicable statutes, regulations and ordinances include any statute, regulation or ordinance that applies to the provider, such as requirements governing Department of State professional licensing, Federal and State wage and hour provisions, local wage standards, Department of Revenue tax law, Department of Environmental Protection safe waste disposal, child and adult protective services, fair housing, insurance, Workforce Innovations and Opportunities Act and OSHA health and safety rules.

General—Inclusion of autism services

A few advocacy organizations, a county government and a provider support the inclusion of autism services within the five chapters of regulations. One advocacy organization asked the Department to go a step further and include programs serving individuals with other disabilities and medical conditions, including cerebral palsy, muscular dystrophy, spina bifida, paralysis and respiratory disease. Several commentators ask that there be no exemptions from Chapter 6100 for autism services.

Response

The Department agrees with the positive movement to align services for individuals with autism with services for individuals with an intellectual disability. While the types of treatment, interventions and services vary based on individual needs, an individual with autism and an individual with an intellectual disability share similar protection and funding needs. It is reasonable and efficient to combine these two disability types into comprehensive and coordinated program, operational, funding and licensing regulations. The majority of providers of autism services also provide intellectual disability services. Further, given the significant co-occurrence of intellectual disability and autism diagnoses, alignment of services will result in better coordination and quality of services for an individual with co-occurring diagnoses.

Amendments have been made to Chapters 6400 and 6500 to include autism in the scope of licensing for community homes for individuals with an intellectual disability or autism. See the amended title of Chapter 6400 and §§ 6400.1—6400.4, 6400.15 and 6500.1—6500.4. Because the current regulation at § 2380.3 (relating to definitions; definition of individual) and § 2390.5 (relating to definitions; definition of disabled adult) specifically includes autism, no changes were made to Chapters 2380 and 2390.

Based on public comment, the exemptions for autism services in proposed § 6100.801 (relating to adult autism waiver) have been deleted. The proposed five exemptions are no longer necessary for autism services.

While the Department recognizes the need for services for individuals with other types of disabilities and medical conditions, the regulation encompasses only individuals provided services through the ODP service system.

General—Children's services

The IRRC and several commentators ask the Department to convene a subgroup as part of future stakeholder meetings to focus on addressing children's issues, such as facility use by children, engagement of parents or guardians of minor children, preadmission determinations and planning, education and coordination with other State agencies. Commentators from universities, families, advocacy organizations and providers ask the Department to promote permanency planning to move children from institutional settings to life sharing homes, small family settings and very small community homes. Commentators ask the Department to address rights, planning, data sharing across service systems, parental decision-making and finances for children.

Response

The Department agrees and adds §§ 6100.56, 6400.25 and 6500.26 (relating to children's services) to address children's rights, decision-making and planning and to require the individual plan to include outcomes related to strengthening or securing a permanent caregiving relationship for the child. The Department is committed to continuously improve the planning, communication and data sharing for children's services across the Department and will seek stakeholder input on children's issues, as necessary, in the future.

General—Definitions

Numerous commentators suggest relocating definitions and adding definitions. One commentator asks to place all definitions in one chapter, rather than list definitions in each of the five chapters. Several commentators, plus numerous form letters from commentators, ask to locate all definitions in the beginning of each chapter, rather than disperse the definitions throughout the chapter. The IRRC asks to locate the definitions that apply throughout a chapter to the general definition section. The IRRC asks to locate definitions to the beginning of a particular section, if the definition applies only to one section. The IRRC asks that terms be used consistently across the chapters.

Response

The Department follows the guidelines for the location of the definitions as described by the *Pennsylvania Code and Bulletin Style Manual, Fifth Edition* as published by the Legislative Reference Bureau, § 2.11 (relating to definition section).

Terms are used consistently throughout each chapter; however, due to the nature of the amendments of the five chapters, sometimes different terms are used in Chapter 6100 and the four licensing chapters to adapt to the existing language of the licensing chapters. For example, in § 6100.404 (relating to final incident report) the term "provider" is used consistent with its use throughout Chapter 6100; however, § 2380.17 (relating to incident report and investigation) uses the term "facility;" the term "facility" is necessary to maintain compatibility with the language used throughout Chapter 2380. Because Chapter 2380 is not being revised in its entirety, the amended terminology must be consistent with the existing terms used in Chapter 2380.

Definitions of "cost report," "health care practitioner," "individual plan," "life sharer," "service," "support," "TSM-targeted support management" and "volunteer" are added to § 6100.3 (relating to

definitions). Definitions of "health care practitioner," "individual plan" and "volunteer" are added to §§ 2380.3, 2390.5 and 6400.4 (relating to definitions). Definitions of "health care practitioner," "individual plan" and "life sharing home or home" are added to § 6500.4 (relating to definitions). Several of the requested definitions are not added as the dictionary meaning applies or because the term is not used in the chapter.

General—Terminology

Several commentators, plus numerous form letters from commentators, recommend the use of terms other than "client," "facility" and "program." The commentators suggest the use of "individual," "home" and "provider."

Response

Chapter 6100 does not use the term "facility" or "client;" rather, Chapter 6100 uses the terms "service location," "individual" and "provider." The term "program" is used only in a broad sense referencing a special program type, such as agency with choice (AWC) or vendor goods and services; an HCBS program; or a county program.

As discussed previously, the four licensing chapters must continue to use terms as used throughout the existing chapters. The term "facility" is necessary to maintain compatibility with the language used throughout Chapter 2380. The term "client" is necessary to maintain compatibility throughout Chapter 2390.

General—Changes to licensing regulations not subject to revision

Numerous commentators and the IRRC suggest changes to sections of the licensing regulations that are not proposed for revisions. For example, the IRRC and a few commentators suggest changes to the program specialist qualifications in §§ 2380.33(c), 2390.33(c) and 6400.44(c) (relating to program specialist). The IRRC and other commentators ask to explain the inconsistencies of the program specialist qualifications across the licensing chapters and why work experience is not included as a qualification. The IRRC asks to explain the apparent staff ratio conflicts in § 2380.35 (relating to staffing). A commentator suggests changes to the staffing ratios in § 2380.35. The IRRC asks about the differences between a full and partial assessment in §§ 2380.181, 2390.151, 6400.181 and 6500.151.

Response

In accordance with the act of July 31, 1968 (P.L. 769, No. 240), known as the Commonwealth Documents Law, the Department may make "such modifications to the proposed text as published pursuant to section 201 as do not enlarge its original purpose." 45 P.S. § 1202. The Department is therefore prohibited from making substantive changes to sections of regulations if no substantive revisions were proposed. In the examples of §§ 2380.33(c) and 6400.44(c), amendments were proposed to §§ 2380.33(b) and 6400.44(b) only. The Legislative Reference Bureau printed the existing subsection (c) for clarity purposes only. In the example of § 2380.35, the only proposed change was non-substantive in nature changing the term "ISP" to "PSP;" therefore, the Department is prohibited from making substantive changes to this section.

The Department is prohibited from making substantive changes in the final-form regulation if no substantive changes were proposed, including for example §§ 2380.33(a), 2380.35(b), 2380.36(b), 2380.36(c) and 2380.181(b).

In response to the comment about the inconsistency of the program specialist qualifications, the applicability and services for the four licensing chapters vary greatly, warranting differences in staff qualifications, titles and ratios. Work experience alone without higher education is not acceptable

for a program specialist, due to the professional duties and responsibilities of the program specialist. In response to the comment about the conflicting requirements regarding the adult training facility staff ratios, the staff ratio requirements for adult training facilities have been in effect since 1993 with no conflict or concern.

Both §§ 2380.35(a) and 2380.35(c) apply, without conflict. The requirement of one direct service worker for every six individuals in subsection (a) requires the staff person to be "physically present," meaning in the same room or program area. The requirement of two staff persons being present at all times in subsection (c) requires the staff person to be present in the facility and not necessarily physically present with individuals. This is required so there is staff back-up in the event of an emergency. No substantive revisions were proposed to § 2390.151 (relating to assessment), so the Department is prohibited from making substantive changes in the final-form regulation. Section 2390.151(a) refers to an initial assessment and updated assessment. The updated assessment contains updated information from the initial assessment based on the individual's needs.

General—Language

Numerous commentators suggest revised language for multiple sections of the proposed regulation, such as revised language to: delete "the purpose of this chapter is to" and substitute alternate language using the verb "governs" in § 6100.1 (relating to purpose), add new language to § 6100.1 regarding the provisions of the subsections, use both the male and female gender and change the use of the terms "shall", "must" and "will."

Response

The Department reviewed and considered all suggested language changes. In some cases, the suggested revised language is used in the final-form regulation; however, in many cases the suggested language changes the intent of the regulation with no corresponding explanatory comment, the added language is unnecessary or the proposed rewrite violates the drafting procedures of the *Pennsylvania Code and Bulletin Style Manual*, including *Pennsylvania Code* formatting; use of plural versus singular; and the use of terminology such as "each," "any," "a," "an," "shall," "may," "will" and "must." See *Pennsylvania Code and Bulletin Style Manual, Fifth Edition*, 2014, Legislative Reference Bureau.

General—Chapter 6100

The IRRC, a provider association and numerous form letters from commentators state that there are conflicts between the Federal waivers and the proposed regulation. The IRRC also states that commentators request intended mandatory provisions of the Federal waivers be reflected in the regulation consistent with State statute and applicable case law. The commentators state that the mandatory provisions in the waivers cannot be adopted by reference in a regulation. The IRRC asks the Department to conform to the intent of the General Assembly to set clear standards for the regulated community.

Response

In response to questions about the Department's authority to enforce the Federal waivers through incorporation by reference in the regulation, the Department decided to delete such references throughout Chapter 6100. There is no conflict between the Federal waivers and the final-form regulation, and therefore it is unnecessary to address any conflict. In addition, CMS requirements related to quality management, health and safety, incident management, individual rights, individual planning, HCBS settings, rate setting and provider enrollment are addressed in Chapter 6100. See 42 CFR §§ 441.300—441.310, 441.350—441.365.

§ 6100.1(a)—Purpose

A provider association, plus numerous form letters from commentators, request the addition of payment requirements to the purpose statement.

Response

The Department has added payment requirements to the purpose statement.

§ 6100.1(b)—Purpose

Commentators suggested adding a reference to the Department's Everyday Lives document.

Response

The Department appreciates the acknowledgement of the Everyday Lives document as revised and reissued in July 2016; however, the Everyday Lives document is non-regulatory and as such is not appropriate to reference in regulation.

§ 6100.2—Applicability

One commentator asks to clarify that Chapter 6100 applies only to ODP-funded programs and that the chapter does not apply to individuals funded through other states or individuals funded through private funds, private insurance, schools or child welfare systems. One commentator asks for a much broader scope for Chapter 6100, including children's service waivers, the Omnibus Budget Reconciliation Act (OBRA) waiver, the Office of Long-Term Living waiver, the Community HealthChoices (CHC) waiver, State-plan applied behavioral analysis services and Chapter 3800 (relating to child residential and day treatment facilities). One commentator asks to exempt services for older adults.

Response

Section 6100.2 (relating to applicability) is clear. Chapter 6100 does not apply to individuals funded by other states or individuals funded through private funds or private insurance. The chapter does not apply to funding provided through a source, including managed care or a Federal waiver program, that is not funded through the Department for individuals with an intellectual disability or autism. The chapter applies if a child receives services in a child residential facility governed by Chapter 3800, for which HCBS funding is provided by the Department for individuals with an intellectual disability or autism. The ODP adult autism waiver does not include services for children. The chapter applies to older adults if the services are funded through the Department for individuals with an intellectual disability or autism.

§ 6100.2(c)—Applicability

A county government association and numerous individual county governments commend the Department for developing a foundational set of regulations, including base-funding, to emphasize the crucial components of services such as the person-centered planning process. A few commentators ask to emphasize that Chapter 4300 (relating to county mental health and intellectual disability fiscal manual) continues to govern the fiscal operations of base-funding services and that the county intellectual disability and autism programs have flexibility to cover needed services with base-funding. A provider asks that Chapter 6100 not apply to base-funding services, arguing that Chapter 4300 is sufficient. A few providers ask to delete Chapter 4300 and apply the Chapter 6100 payment provisions to base-funding. A provider association asks to allow regulatory waivers for base-funding services to continue to permit flexibility.

Response

Chapter 4300 continues to apply to base-funding services to provide a method for a county intellectual disability and autism program to fund a special service for an individual if an HCBS is not available or if the individual is not eligible for an HCBS. County intellectual disability and autism programs continue to have flexibility to cover needed services with base-funding.

Chapter 4300 is appropriate for base-funding only services, since this chapter provides a baseline of payment provisions that are unencumbered by Federal regulations and procedures.

The program requirements of Chapter 6100, including criminal history record checks in § 6100.47 (relating to criminal history checks); staff training in §§ 6100.141—6100.143 (relating to training); individual planning in §§ 6100.221—6100.225; and restrictive procedures in §§ 6100.341—6100.350 are important protections for all individuals regardless of the ODP funding sources. Conformity of program requirements across funding sources permits a seamless and efficient transition as an individual transitions from one funding source to another within the ODP service system.

With respect to the comment on the need for regulatory waivers, such waivers are permitted in accordance with § 6100.43 (relating to regulatory waiver).

§ 6500.3(f)(1)—Applicability

An advocacy organization objects to the exclusion of services provided by relatives in licensed life sharing homes.

Response

The private home of a person who is rendering services to a relative is a statutory exemption in Article X of the Human Services Code. See 62 P.S. § 1001, definition of mental health establishment. Chapter 6100 applies to services provided by a relative, such as unlicensed life sharing that is exempt from licensure under Chapter 6500.

§ 6100.3—Definition of cost report

In accordance with comments from the IRRC, the definition of "cost report" is relocated from proposed § 6100.643(a) (relating to submission of cost report) to § 6100.3 (relating to definitions) since this term is used in several sections of the chapter. The definition of "cost report" is unchanged from the proposed rulemaking.

§ 6100.3—Definition of designated managing entity

One commentator supports change of the term "administrative entity" to "designated managing entity" to emphasize management function and the authority to act. One commentator asks not to use the acronym DME, as DME means durable medical equipment in other departmental programs.

Response

No change is made to this definition. DME is not used in the proposed rulemaking or the final-form regulation.

§ 6100.3—Definitions of eligible cost, natural support and OVR

The terms "eligible cost" and "natural support" and the acronym "OVR" are deleted as these terms and acronyms are no longer used in this chapter.

§ 6100.3—Definition of family

Several commentators ask to delete the term "family" and the definition of "family," but rather to refer to persons designated by the individual throughout the regulation, as applicable.

Response

This change is made. The individual may choose to involve, or not to involve, specific family members, friends or advocates in planning activities and decision-making. Necessary and appropriate references to family, such as in § 6100.53 (relating to conflict of interest), are changed to relative.

§§ 2380.3, 2390.5, 6100.3, 6400.4 and 6500.4—Definition of individual plan

The acronym "PSP" is changed to "individual plan" because it reflects current ODP service system terminology. A definition of "individual plan" is added in each section.

§ 6100.3—Definition of life sharer

In consideration of the possible unintended consequences related to employee-employer relationships, a definition of "life sharer" is added to clarify that the term includes both an employee life sharer and a contracted life sharer.

§ 6100.3—Definitions of support and service

A few commentators agree to the proposed term "support" throughout the chapter; however, several commentators, plus numerous form letters from commentators, ask to use the term "service" rather than "support." Several commentators ask to define the terms "service" and "support." Several commentators ask to use a different term than "natural support" for one who provides unpaid and informal assistance.

Response

The terms "support" and "service" are defined. "Service" means a paid HCBS, support coordination, TSM, agency with choice, organized health care delivery system, vendor goods and services and base-funding while "support" means an unpaid activity or assistance provided to an individual that is not planned or arranged by a provider. When used as a verb, "support" is changed to "assist." These changes in terminology are applied consistently to numerous sections of the final-form regulation. The term "natural support" is deleted.

§§ 2380.3, 2390.5, 6100.3 and 6400.4—Definition of volunteer

Numerous commentators and the work group ask to add a definition of "volunteer" to mean a person who engages in an activity that is an organized and scheduled component of the service system and who is not compensated for such activity.

Response

This change is made. "Volunteer" is defined to mean a person who is an organized and scheduled component of the service system who does not receive compensation, but who provides a service through the provider that recruits, plans and organizes duties and assignments. A volunteer does not include a person who provides intermittent and ancillary assistance, such as housekeeping or entertainment. A volunteer does not include an individual's friends or relatives, unless they work as part of an organized volunteer program.

A definition of "volunteer" is not added to Chapter 6500 because the term "volunteer" is not used in the same context in which it is defined in the other chapters. Volunteers are not part of the routine service system for life sharing homes.

§§ 2380.3, 2390.5, 6100.3, 6400.4 and 6500.4—Definitions of abuse, neglect and exploitation

Several commentators ask to add the definitions of "abuse," "neglect" and "exploitation."

Response

These definitions are not added. The terms "abuse," "neglect" and "exploitation" are defined differently in the applicable statutes and regulations. For example, in the Child Protective Services Law (23 Pa.C.S. § 6303), the term "child abuse" includes forms of both neglect and exploitation; while in the Adult Protective Services Act (35 P.S. § 10210.103) and the Older Adults Protective Services Act (35 P.S. § 10225.103), the terms "abandonment," "abuse," "exploitation" and "neglect" are defined separately. The intent of this section is to use the broad term "abuse" and reference the applicable statutes and regulations, including the Adult Protective Services Act (35 P.S. §§ 10210.101—10210.704) and applicable regulations, the Child Protective Services Law (23 Pa.C.S. §§ 6301—6386) and applicable regulations and the Older Adults Protective Services Act (35 P.S. §§ 10225.101—10225.5102) and applicable regulations. As Pennsylvania's protective services laws and terms evolve, the broad reference to applicable statutes and regulations will remain current. Citing and defining the various terms used in existing statutes and regulations serves no purpose and may quickly antiquate the final-form regulation.

§ 6500.4—Definitions

A provider association asks to delete all references to "staff," as there are no staff in life sharing.

Response

The term "staff" is not used in any of the proposed definitions; however, the life sharing specialist and other life sharing agency staff are considered staff persons and as such there are some uses of "staff" in this chapter.

§ 6100.41—Appeals

One commentator suggests that provider appeals not be limited to Chapter 41 (relating to medical assistance provider appeal procedures).

Response

No change is made. Provider appeals are regulated in Chapter 41, which provides detailed provisions governing the practice and procedures in medical assistance provider appeals commencing on or after November 25, 2006. See 55 Pa. Code § 41.1 (relating to scope). Adding additional appeal processes would create duplicative and potentially conflicting processes and is unnecessary.

§ 6100.42(a)—Monitoring compliance

Several commentators request that only one designated managing entity review a provider, rather than multiple designated managing entities. A few commentators suggest a coordinated effort between licensing, fiscal auditing and provider monitoring. Several commentators suggest that this section be renamed "provider performance review." A provider association, plus numerous form letters from commentators, ask to clarify that only department pre-approved monitoring methods be used and that the specific time frames for the various monitoring functions be included.

Response

No change is made to this subsection.

One objective in aligning multiple chapters of regulations is to improve coordination and implement a more streamlined approach to provider monitoring. The Department will typically assign one designated managing entity to monitor regulatory compliance. The Department maintains the authority to assign more than one designated managing entity in situations that warrant such an assignment due to the size and geographic coverage of a provider.

This section is properly named since it addresses multiple types of reviews and audits. The Department will determine the appropriate monitoring tools, methods and time frames. The monitoring tools, methods and time frames are not specified in the regulation because they are subject to change based on Federal and State requirements relating to auditing assurances.

§ 6100.42(b)—Monitoring compliance

A few commentators ask to delete this proposed subsection as it is too vague.

Response

This subsection is shortened and clarified to allow the Department and the designated managing entity free and full access to the provider's policies and records and the individuals receiving services in accordance with this chapter.

§ 6100.42(c)—Monitoring compliance

A few advocates and a provider ask to delete the three time frames.

Response

The Department agrees and has made this change.

§ 6100.42(d)—Monitoring compliance

A provider association, plus numerous form letters from commentators, ask to delete the reference to the required format of the various regulatory agencies and allow the provider to determine a reasonable format for submission of the corrective action plan.

Response

No change is made. Each monitoring agency, such as the Department's Bureau of Financial Operations for financial audits and the ODP for provider monitoring, has a data collection format to provide for efficient and automated data collection, tracking, review and analysis.

§ 6100.42(e)—Monitoring compliance

The IRRC and several providers ask to explain why a corrective action plan is required for an alleged violation. A few commentators object to the time frame for submission of a corrective action plan. One commentator asks to mandate that the provider and the Department work in cooperation to develop the corrective action plan. Several commentators, plus numerous form letters from commentators, ask to change the term "violation" to "non-compliance."

Response

The intent of the proposed language "alleged violation" is to allow the provider an opportunity to challenge the alleged non-compliance on the corrective action plan form prior to deeming the non-compliance final. To clarify, the language is revised to reference a preliminary determination of non-compliance, rather than an alleged violation. If the Department or a designated managing entity preliminarily determines non-compliance with this chapter, the provider may respond with a

challenge to the preliminary determination by providing evidence of regulatory compliance, prior to completing the corrective action plan.

No timeline for return of a corrective action plan is prescribed in either the proposed rulemaking or the final-form regulation. The timelines for completing the corrective action plan will be determined by the Department based on the number and types of non-compliance.

The Department will assist and advise the provider in the development of an effective corrective action plan as necessary to achieve and maintain regulatory compliance.

The term "violation" is changed to "non-compliance."

§ 6100.42(h), (i)—Monitoring compliance

Several commentators ask to delete these subsections as they are overly prescriptive, unnecessary and conflict with the requirements relating to eligible cost.

Response

These two subsections are deleted.

§ 6100.42(i) (§ 6100.42(k) in proposed rulemaking)—Monitoring compliance

A provider association, plus numerous form letters from commentators, ask the Department to specify the time period for keeping documentation.

Response

The time period for retaining all records, including the regulatory compliance documentation, is specified in § 6100.54 (relating to recordkeeping).

§ 6100.43(a)—Regulatory waiver

A few county governments and a family representative support the proposed regulatory waiver section and agree that waivers should be prohibited for rights and restrictive procedures. A few additional families and a provider support the prohibition of waivers on the rights section. A provider association believes that the waiver conditions in proposed subsection (c)(2) and (c)(3) are unnecessary and that there should be no list of regulations for which a waiver may not be granted. A provider association, plus numerous form letters from commentators, ask to allow waivers for rights and restrictive procedures to address the needs of individuals such as an individual with Prader Willi syndrome or an individual who is a sexual offender. A few providers and families request clarification regarding § 6100.223(8) and (9) (relating to content of the individual plan), suggesting that any modification of rights relating to a significant health and safety risk to the individual or others be addressed through the individual plan process.

A few providers believe this section focuses on penalties and remedial actions. A few providers ask the Department to respond timely to waiver requests. A provider association asks to relocate the prohibitions for a waiver to each applicable section, rather than state the waiver requirements together near the beginning of the chapter. A few provider associations, plus numerous form letters from commentators, ask to change the term "waiver" to "exception."

Response

As suggested, the reference to the Federally-approved waivers in proposed subsection (c)(3) is removed. No other changes are made.

The granting of waivers is at the sole discretion of the Department. The Department is not obligated to entertain regulatory waivers, nor does the provider have the right to a waiver; however, in the spirit of openness and cooperation, the Department desires to permit providers the opportunity to request a waiver in certain circumstances and for certain sections of the regulation. The majority of the regulatory requirements of this chapter are open to a request for a waiver; only the administration requirements, individual rights and restrictive procedures are excluded from requests for waivers since these sections provide the framework for the HCBS program and protect the individuals from mistreatment and abuse.

As suggested by commentators and the work group, the concerns expressed regarding specific risks to an individual's health and safety such as an individual with an eating disorder, food allergy, criminal behavior and other behavior that creates a serious health and safety risk to the individual or others are addressed in § 6100.223(8) and (9). The individual plan team will appropriately address the protection needs of an individual relating to specific behaviors that may pose a significant health and safety risk to the individual or others. Addressing the specific significant health and safety needs of the individual through the planning process is more appropriate, timely and reasonable than utilizing a formal departmental waiver process.

This section does not focus on remedial action; rather, the Department is permitting a provider the option to request a regulatory waiver.

The Department will respond timely to each waiver request. Providers can speed the review and decision on a waiver request by using the Department's required form and completing each section of the form accurately and thoroughly.

The section on waivers is properly located near the beginning of the chapter under General Requirements, rather than dispersing and repeating the requirements and prohibitions throughout the chapter. The term "waiver" is correct based on the provision in 1 Pa. Code § 35.18 (relating to petitions for issuance, amendment, waiver or deletion of regulations) governing the submission of waiver requests.

§ 6100.43(c)—Regulatory waiver

A provider association, plus numerous form letters from commentators, ask the Department to recognize that there are times when a request for a waiver may infringe on community integration and independence to protect the health and safety of the individual. A provider asks the Department to require waivers to be added to the individual plan.

Response

The conditions for a waiver include the requirement that the provider demonstrate how granting of the waiver will increase person-centered approaches, integration, independence, choice or community participation for an individual or a group of individuals. The waiver justification must show how any one or more of these criteria are met.

While a regulatory waiver may be appropriate to discuss during the individual plan meeting, inclusion of the waiver decision in the individual plan is not a regulatory requirement. Including specific regulatory waivers in each applicable individual plan is an unnecessary administrative burden on the provider. A regulatory waiver may relate to an individual, but more likely may apply to a group of individuals within the provider agency. A regulatory waiver involves formal processes and compliance monitoring that occur outside the individual planning process. The individual plan includes the services and supports necessary to assist the individual to achieve the desired outcomes. If a regulatory waiver relates to an individual's services and supports, the individual plan will reference the existence of a regulatory waiver in describing the services and supports.

§ 6100.43(d)—Regulatory waiver

A provider association and several providers ask to issue non-expiring waivers, rather than require an annual waiver renewal, putting a provider at risk of a regulatory citation.

Response

The Department will include an expiration date for each waiver that is granted; however, some waivers may be granted based on a certain condition and not necessarily contain a precise end date. It is the provider's responsibility to monitor compliance with the waiver conditions, track the waiver expiration date, if applicable, assess the need for a continuation of the waiver and request a waiver renewal. There is no annual waiver renewal requirement provided in the final-form regulation. Section 6100.43(d) is written to account for both time-limited and extended time regulatory waiver situations.

§ 6100.43(e)—Regulatory waiver

A provider association asks for a clear time frame for the individual to respond and to limit the time frame to no more than 45 days. An advocacy organization and a provider ask to allow a shorter time frame for an individual response, if all parties agree.

Response

This subsection was revised to eliminate the requirement for the individuals to review and respond to the request. The individual receives notification of the waiver request only. The proposed time frames created an unnecessary administrative burden on providers and individuals.

§ 6100.43(f), (g), (h) and (i)—Regulatory waiver

The IRRC, a provider association, plus numerous form letters from commentators and a few providers, ask to provide an exception to the time frames or to presume the waiver will be granted with a follow-up to formally secure the waiver in the case of immediate jeopardy to the individual's health and safety.

Response

In response to comments, proposed subsections (f), (g), (h) and (i) are deleted. Section 6100.43 is simplified to clarify the steps in requesting and obtaining a waiver. There is no longer a requirement to submit the waiver to individuals in advance of the submission of the waiver request. A copy of the waiver is shared with the individuals at the same time it is submitted to the Department; therefore, an exception to the time frames is not necessary. Each waiver request must be reviewed by the Department to assure the protection of the health and safety of the individual; a waiver cannot be presumed granted. The Department will conduct an expedited review and decision in the case of immediate jeopardy to an individual's health and safety. The removal of the time frames in the proposed § 6100.43(d) allows a fast-track waiver decision by both the provider and the Department.

§ 6100.43(l)—Regulatory waiver

A provider asks how compliance with the notification requirement will be measured and tracked by the Department.

Response

Subsection (l) is deleted because it is redundant. A provider must notify affected individuals as required in § 6100.43(f). It will not be necessary to measure or track regulatory compliance

regarding notification.

§ 6100.44—Innovation project

Numerous commentators applaud the Department for encouraging new ideas to emerge and promoting innovation to increase integration, independence and choice. A provider association, plus numerous form letters from commentators, note that innovation opportunities could be moot if sufficient waiver funding is not available. A provider suggests that true innovation lies outside the realm of regulation and that innovation should be addressed by a departmental bulletin and not through regulation. Several commentators ask that the innovation projects be made public to share new ideas and successful models. A few county governments ask that an approved innovation project be shared with the County Intellectual Disability and Autism Office. A commentator asks for a standard form for submission of an innovation project proposal. An advocacy organization and a few providers ask for innovation projects to be granted on a permanent basis.

Response

The Department supports and promotes new and innovative service concepts, staffing designs, community integration approaches and person-centered models.

An approved innovation project is public information and will be shared with the affected County Intellectual Disability and Autism Offices.

Because this is a proposal for a new and different service model, it does not lend itself to a Department-mandated form; however, a provider should follow the outline in this section to be certain all components are addressed in the proposal.

The Department notes that there is no current appropriation for HCBS innovation projects and that all approvals to use HCBS monies must meet the Federal waiver requirements.

The Department is not prohibited from addressing innovation projects through a departmental bulletin.

§ 6100.44(b)—(d)—Innovation project

Several commentators ask to add or delete items from the list of the components of an innovation project proposal. Commentators suggest the deletion of the proposed § 6100.44(b)(1)—(5), (d) and (f). A provider association, plus numerous form letters from commentators, state that it is unnecessary to create a new committee, but rather the agency's board may satisfy this requirement. A commentator asks to combine § 6100.44(b)(8)—(10). Commentators suggest the additions of business partners and employment.

Response

Several changes are made to shorten and simplify this section. Proposed subsections (b)(2), (b)(14), (b)(15), (c), (d)(3), (e), (f) and (g) are deleted because those proposed provisions are cumbersome and unnecessary. Final-form subsections (b)(1)—(10), (c)(1)—(4) and (d) ((b)(1), (b)(3)—(5), (d)(1)—(2) and (d)(4)—(5) in proposed rulemaking) are retained because they provide important conditions that must be described and reviewed for the Department to consider an innovation project.

Proposed subsection (b)(8)—(10) are shortened and collapsed into one paragraph. The reference to an advisory committee in proposed subsection (b)(8) is deleted; this allows the provider's board or another existing group to advise the innovation project in the final-form regulation subsection (b)(7). Community partners in the final-form regulation subsection (b)(7) include business partners.

While an innovation project may address employment, it is not a necessary component for each innovation project.

§ 6100.45—Quality management

Numerous commentators suggest that the proposed quality management requirements are vague, burdensome and overly prescriptive. The IRRC and numerous commentators state that the proposed requirements will result in increased paperwork to track the data, particularly for proposed § 6100.45(b)(1), (6) and (7). Commentators state that mandating performance data review in the proposed nine areas will require a new part-time staff positon to enter, track and monitor the quality management data. Commentators argue that the specific and detailed plan components will reduce the agency's ownership of the plan. Some suggest issuing a departmental bulletin as best practice, rather than attempting to mandate quality management practices through regulation.

A provider association, plus numerous form letters from commentators and ten providers, state that progress outcomes should be evaluated through the individual planning process, rather than through the quality management process.

Many providers object to requiring individual, family and staff satisfaction surveys. A university, a family group and an advocacy organization support the new requirement for family and individual satisfaction surveys.

A provider association, plus numerous form letters from commentators, request that the quality management form not be mandated.

The IRRC asks the Department to address the reasonableness of and need for the quality management review requirement, as well as the economic impact of this proposed requirement.

Response

The Department listened to the overwhelming public objections to this section and significantly reduced the content and specificity of this section. The proposed list of nine specific areas to be reviewed and evaluated in the quality management plan is restructured and reduced to five broad components, including performance measures; performance improvement targets and strategies; feedback methods, including feedback from individuals and staff; data sources; and the role of the quality management staff. These five broad component areas allow the provider significant discretion to design a quality management plan that meets the provider's needs to target specific goals and establish priorities. While quality management review regulatory provisions are essential, the detail contained in the proposed rulemaking is not necessary. A departmental bulletin may provide best practice recommendations, but the basic provisions for a provider to maintain a quality management program must be in regulation to provide an enforceable mandate.

Quality management is a systemic overview of the provider's organization as a whole, including its processes, procedures, system outcomes and areas for improvement. The individual planning process focuses on the specific strengths, preferences and services for each individual. As suggested, an individual's progress and outcomes will continue to be reviewed through the individual planning process.

The proposed requirement for the provider to conduct individual, family and staff satisfaction surveys is deleted in response to comments; however, the provider's quality management plan must include the provider's methods to obtain feedback relating to personal experience from individuals, staff persons and other affected parties.

Use of a departmental quality management form is not required.

Although no specific comments were received asking to change the quality management review timeline, based on numerous comments asking to reduce the overall quality management requirements, the Department extended the timeline for analysis and revision of the quality management plan from 2 years to 3 years, to align the provider's quality management analysis and revisions with the provider monitoring cycle.

No new staff positions are required and no added paperwork is necessary to meet § 6100.45, since the providers currently have a quality management plan in accordance with prior departmental guidance and direction. Given the revisions of this section, particularly to delete the proposed requirements for trend analysis of data and satisfaction surveys and the requirement to review and document progress on the quality management plan quarterly, there is no economic impact related to compliance with § 6100.45.

§ 6100.46—Protective services

The IRRC, an advocacy organization and a family ask why the terms "neglect" and "exploitation" are not included in this section. The IRRC notes that these two terms are used in the incident management sections of the five chapters. The IRRC asks the reasonableness of not including "neglect" and "exploitation" in this section and how this protects the public health, safety and well-being.

The IRRC and several providers ask to take into account other possible outcomes of an investigation, such as an inconclusive and unconfirmed finding. A few provider associations, plus numerous form letters from commentators and several providers, mention that some abuse allegations are reported to multiple State agencies and by multiple sources; clarification is requested regarding the need for multiple reports.

The IRRC and several providers ask if the Department considered restricting the staff person, consultant, intern or volunteer from having access to any individual and not just the alleged victim. A provider asks to delete the restriction to separate the alleged abuser from the alleged victim and permit the alleged abuser to be present with the alleged victim before the investigation is concluded. A provider association, plus numerous form letters from commentators and a provider, ask not to usurp the provider's disciplinary action, but rather to lift the restriction after the provider concludes the internal investigation. The IRRC asks the Department to explain the reasonableness of this provision and how the public health, safety and well-being is protected. A county government commentator asks that timelines be established for the dates of the criminal history checks.

A family and an advocacy organization ask that families be informed of the abuse allegation. A provider asks that the support coordinator be informed of the abuse allegation. A provider association states that the reporting in § 6100.46(c) is redundant of the incident reporting in §§ 6100.401—6100.405. Several providers ask to clarify the county program responsibility in § 6100.46(c)(5) if no funds are received from the county program.

Response

The terms "abuse," "neglect" and "exploitation" are defined differently in the applicable statutes and regulations. For example, in the Child Protective Services Law (23 Pa.C.S. § 6303), the term "child abuse" includes forms of both neglect and exploitation; while in the Adult Protective Services Act (35 P.S. § 10210.103) and the Older Adults Protective Services Act (35 P.S. § 10225.103), the terms "abandonment," "abuse," "exploitation" and "neglect" are defined separately. The intent of this section is to use the broad term "abuse" and reference the applicable statutes and regulations, including the Adult Protective Services Act (35 P.S. §§ 10210.101—10210.704), the Child Protective Services Law (23 Pa.C.S. §§ 6301—6386), the Older Adults Protective Services Act (35 P.S. §§ 10225.101—10225.5102) and applicable regulations. As Pennsylvania's protective services laws and terms evolve, the broad reference to applicable statutes and regulations will remain

current. Citing and defining the variable terms used in existing protective services statutes and regulations serves no purpose and may quickly antiquate Chapter 6100. It is reasonable and appropriate to protect the public health, safety and well-being by relying on the applicable protective services statutes and regulations to govern the scope, types and definitions of abuse for the purposes of abuse reporting and investigation.

As the IRRC notes, the terms "neglect" and "exploitation" are used in the incident management sections of the five chapters. See §§ 2380.17, 2390.18, 6100.401, 6400.18 and 6500.20. It is necessary to list all possible types of abuse-related incidents, including "neglect" and "exploitation," in the incident management sections of the regulations, since incident management is generally governed through regulation, rather than by other applicable protective services statutes and regulations.

The Department clarified that the staffing restriction is lifted if there is an inconclusive finding by the authorized investigating agency.

In § 6100.46(b), the use of the term "an" in the phrase ". . .may not have direct contact with an individual until the investigation is concluded. . ." includes any individual and not just the alleged victim. The term "an" means "any" in accordance with the *Pennsylvania Code and Bulletin Style Manual, Fifth Edition*, § 9.3(a) (relating to use of "a," "an," "the," "each" and "every"). This subsection prohibits an alleged perpetrator of abuse from having direct contact with any individual until the investigation by the authorized investigating agency concludes that no abuse occurred or that the findings are inconclusive. Findings from an internal provider investigation are not sufficient to permit an alleged perpetrator of abuse to work directly with individuals. The provider's disciplinary process complements, but does not replace the protections from abuse afforded by statutes and regulations. This provision protects the health, safety and well-being of the individuals by restricting the alleged perpetrator from access to all individuals while under an abuse investigation.

The due dates of the various criminal history checks are governed by applicable statutes and regulations; this is not under the Department's purview to alter.

In many cases, the family will be informed of an allegation of abuse in accordance with § 6100.46(c)(2); however, the ultimate decision of whether to inform a family member of an allegation of abuse lies with the adult individual. If the individual is a child, the child's parent or legal guardian will be informed of the alleged abuse in accordance with § 6100.56 (relating to children's services).

The support coordinator receives notice of incidents, including abuse reports, through the Department's electronic incident management system.

The term "household member" is added to § 6100.46(b) to address a person living in a life sharing home who may pose a risk to an individual. The term "abuse" is removed before the term "investigation" in § 6100.46(b) because it is unnecessary. In § 6100.46(c)(5), the term "if applicable" is added to clarify that this does not apply if no funds are received from the county program.

The abuse reporting required in § 6100.46(c) is governed by State law. The incident reporting in §§ 6100.401—6100.405 is required by the Department to maintain Federal financial participation, to monitor the provision of HCBS and to protect the health and safety of the individuals.

There are multiple State statutes and regulations that require specific types of abuse reporting to different State agencies. This final-form regulation creates no administrative or operational burden regarding abuse reporting, other than that which already exists in law.

Compliance with the final-form regulation can be reasonably met; the requirements are consistent with applicable statutes and regulations. The final-form regulation is essential to protect the health, safety and well-being of the individuals who receive HCBS.

§ 6100.47—Criminal history checks

The IRRC asks the Department to define "household members" and "natural supports," clarify applicability to natural supports and clarify who is exempt from the criminal history checks.

A provider association, plus numerous form letters from commentators, ask to clarify that criminal history checks are not required for children.

There are strong and differing opinions regarding the persons who should be required to have criminal history checks. A home care provider states that it will cost $42 per person to complete the checks. A family organization, an advocacy organization, a family and a provider ask to exempt unpaid household members. Several providers ask to exempt all household members from the criminal history check requirement in subsection (b)(1) of the proposed rulemaking. A provider organization, plus numerous form letters from commentators, ask that only staff persons who have direct contact with individuals be required to obtain the checks, while several providers specifically disagree with the same provider association and support broad-based checks for all staff positions, including ancillary staff. One family, an advocacy organization and a few providers ask to exempt volunteers, as this will discourage community involvement. An advocacy organization supports checks for all volunteers, life sharers and household members. A provider association believes that reference to the Adult Protective Services Act is errantly missing.

Response

The term "natural support" is no longer used in this chapter; rather, "support" is defined based on the activity, rather than the person who provides the support.

The term "household member" is not defined. In accordance with the *Pennsylvania Code and Bulletin Style Manual, Fifth Edition*, § 2.11 (relating to definition section), a word used in its dictionary meaning may not be defined. This chapter intends no special meaning of the terms "household" or "member." The *Merriam-Webster* dictionary defines "household" as "a social unit composed of those living together in the same dwelling." The *Merriam-Webster* dictionary defines "member" as "one of the individuals composing a group." See Merriam-Webster.com. *Merriam-Webster*, n.d. Web. 29 June 2017.

Clarification is added to final-form § 6100.47(a)(3) that only adult household members require checks and not children. Further clarification of the applicability of subsection (a)(3) includes those adult household members residing in licensed and unlicensed life sharing homes and in out-of-home overnight respite services.

At the IRRC's request, final-form subsection (c) states more clearly those who are not required to obtain the criminal history checks.

All staff positions require criminal history checks, including ancillary staff who have no direct contact with an individual. Staff persons who do not have direct contact with individuals may have access to individual records, property or monies providing an opportunity for inappropriate behavior, abuse or criminal activity.

The fee for a Pennsylvania State Police background check is $8.00. The fee for a Pennsylvania child abuse check is $8.00, which is rarely required as approximately 87% of the individuals who receive services under this chapter are adults. The fee for an FBI check is $25.75, which includes fingerprinting. For a person who will provide services to adults, an FBI check is required only if the

person lived outside of Pennsylvania within the past 2 years. See 35 P.S. § 10225.502(a)(2). The Child Protective Services Law (See 23 Pa.C.S. § 6344(b)(3)) requires an FBI check for all paid staff who serve children, and also for volunteers who have lived outside of Pennsylvania within the previous 10 years. The impact of this requirement is limited, however, since only 13% of the individuals covered by the final-form regulation are children. The cost for the majority of prospective staff persons is $8.00. The cost for the background check may be borne by the job applicant or by the provider agency. The cost of conducting criminal history checks for prospective staff is factored into the new HCBS rates.

As discussed with the work group, a "volunteer" is defined as a person who is an organized and scheduled component of the service system and who does not receive compensation, but who provides a service through the provider that recruits, plans and organizes duties and assignments. A volunteer does not include a person who provides intermittent and ancillary assistance, such as sweeping the floors or playing the piano. A volunteer does not include an individual's friends or relatives, unless they work as part of an organized volunteer program. With this clear and narrow definition of "volunteer," the Department determined that background checks must be completed for volunteers to protect the health and safety of the individuals.

Reference to the Adult Protective Services Act is not errantly missing in this section. The Adult Protective Services Act governs the reporting and investigating of abuse, but the law does not require criminal history background checks.

§ 6100.48—Funding, hiring, retention and utilization

A provider association, plus numerous form letters from commentators, ask to reference the Adult Protective Services Act.

A provider association, plus numerous form letters from commentators, ask to discuss the relevant court decisions under the Older Adults Protective Services Act.

Response

Reference to the Adult Protective Services Act is not appropriate for this section as the Adult Protective Services Act governs the reporting and investigating of abuse, but not criminal history checks, the provider's duties relating to the disposition of such checks or hiring.

This section is shortened to require compliance with applicable statutes and regulations. The governing statutes and regulations determine the affected staff persons.

The Department will provide further information on the application of applicable protective services court decisions, statutes and regulations.

§ 6100.49—Child abuse history certification

A commentator requests that the exact requirements of the Child Protective Services Law be specified in the regulation.

Response

The implementation requirements of the Child Protective Services Law are specified in 55 Pa. Code Chapter 3490 (relating to protective services). It is unnecessary to repeat the regulatory provisions in Chapter 6100.

§ 6100.50—Communication

A university and a few county governments strongly support this section as proposed. A provider association asks to clarify that this applies only to the extent understood by the individual. Several providers ask who will pay for these communication services. A provider suggests that this section apply only to licensed facilities and not to all HCBS. An advocacy organization and a few providers ask the Department to provide all forms in all languages, including Braille. A family member asks that the individual be given the option of using assistive communication technology. A provider advises that not all individuals are able to communicate and make informed decisions, even with the use of auxiliary aids. An advocacy organization asks to reference the ADA that requires public accommodations, including the use of auxiliary aids and services when necessary. The same advocacy organization asks to require that auxiliary devices be maintained in working order. A few providers ask to require a physician's order for any communication device. A provider asks to require evaluations by a speech pathologist. A county government asks to mandate that the provider support the use of auxiliary devices.

Response

The Department appreciates the helpful and diverse comments on the topic of communication. Effective and ongoing communication is key to individual learning, developing relationships, expressing choice and reporting harm and is essential to the success of the staff providing the services. If staff persons understand the individual's choices, preferences and dislikes, they will provide services that are effective and person-centered. Every individual has the capacity to communicate through speech, gestures, eye contact or the use of assistive technology.

The commentator is correct that communication must be understood by the individual, to the extent the material can be understood; however, no added regulatory language is necessary. This section applies to all HCBS in order to protect the health, safety and well-being of the individuals.

Proposed subsection (b) is deleted as unnecessary and potentially creating confusion and duplication in provider responsibilities regarding communication. The support coordinator's role includes assuring that an individual's communication needs are met. The individual plan specifies the need, types of devices and services and funding sources to cover needed devices and services. The individual has the option of using assistive technology, but appropriate and necessary assistive technology must be offered.

The Department supports rigorous and continual compliance with the ADA. Compliance with the ADA is required. See § 6100.52 (relating to applicable statutes and regulations).

Communication devices must be maintained in working order in accordance with § 6100.442(b) (relating to physical accessibility).

While a physician or speech pathologist may be helpful to diagnose and treat certain types of auditory conditions, not all individuals with a communication need require an intervention or assessment by a licensed professional. For instance, some communication needs are language-based or behavioral in nature, and staff persons and others familiar with the individual on a daily basis are able to assess and address the communication needs. Some individuals with communication needs benefit from technology, such as communication boards and computers.

The cost of translation to languages other than English is included in the fee schedule rates.

The Department will issue any mandated forms that are used by individuals and families, such as the request for a regulatory waiver and the room and board residency agreement, in Spanish as well as in English and in any other language upon request.

§ 6100.51—Complaints (Grievances in proposed rulemaking)

A few county governments ask to use the term "complaint" rather than "grievance," as "grievance" implies the denial of health care services. An advocacy organization asks to clarify that this section applies to complaints submitted by or on behalf of an individual and not to staff person complaints. The same advocacy organization asks that the individual be able to elevate the complaint to the designated managing entity or to the Department. A provider organization, plus numerous form letters from commentators, ask that this section apply only to complaints about an HCBS. A family organization asks that the individual and the family be informed of the process to submit a complaint, that an individual may also submit complaints to the designated managing entity and the Department and that the support coordinator be required to support the individual throughout the complaint process. A provider asks to add a requirement that the individual sign a statement that an explanation of the complaint process was provided. A provider association and a few advocacy organizations ask to clarify the process if a complaint is anonymous. A provider association and a few providers ask to explain the process to be followed if a complaint is a comment, phone call or in writing. A few provider associations and a few providers, plus numerous form letters from commentators, state that the timelines are unreasonable. The IRRC asks the Department to explain why the timelines are reasonable.

Response

The term "grievance" is changed to "complaint." Subsection (a) is revised to clarify that a complaint relates to a service that is submitted by or on behalf of an individual; it does not include a complaint about a non-HCBS issue or a staff person complaint.

The role of the support coordinator relating to the filing and managing of complaints is not specified in this section; however, in accordance with § 6100.802(a) (relating to support coordination, targeted support management and base-funding support coordination), the support coordinator provides services and supports to locate, coordinate and monitor needed HCBS and other support, which includes providing support to the individual, as needed, throughout the complaint process.

In subsection (b), the individual, and persons designated by the individual, are informed about the right to file a complaint and the procedures to file a complaint upon initial delivery of an HCBS and annually thereafter. While the provider must document compliance with this subsection, in an effort to reduce paperwork, a written signed statement is recommended, but not required.

Subsection (g) is clarified to explain that a complaint as used in this chapter is one submitted by an individual or on behalf of an individual. Subsection (g) explains that a complaint may be received in any format, including oral or written.

Subsection (g) includes anonymous complaints since an anonymous complaint may contain valid concerns to be addressed by the provider; however, the name of the complainant cannot be recorded in paragraph (g)(1) as addressed by the phrase "if known." The follow-up report to the complainant in the new subsection (h) cannot be conducted for an anonymous complaint.

The timeline for the complaint resolution is extended from 21 to 30 days as specified in the new subsection (h). In the unusual event that a provider is unable to resolve the complaint within 30 days due to circumstances outside the provider's control, such as a critical witness that is not reachable or a pending external investigation, the provider should document the circumstances outside the provider's control that prevented the complaint resolution and resolve the complaint immediately following the receipt of the outstanding information. The Department believes the revised timeline is reasonable, allowing sufficient time to investigate and resolve the complaint.

The family member is informed of the complaint findings as specified in the new subsection (h) if the family member reported the complaint on behalf of the individual. Complaints about an HCBS

may be submitted to a designated managing entity or the Department; however, the complaint should first be reported to the provider for prompt resolution.

§§ 2380.156, 2390.176, 6100.52, 6400.196 and 6500.166—Rights team in proposed rulemaking

Numerous commentators representing families, universities, advocacy organizations, county governments, providers and a few provider associations, plus numerous form letters from commentators, object to all or a portion of the proposed § 6100.52 (relating to rights team). While several commentators support the concept of an independent and overarching rights team, the commentators are unanimous that the proposed regulation missed the mark and overextended the role and practical reality of mandating such a team under the purview of a provider.

The IRRC asks to explain the unnecessary bureaucratic layer, additional administrative duties, costs and paperwork imposed by this proposed section. Numerous commentators state that the proposed role of the rights team overlaps and duplicates the roles and procedures of the restrictive procedure process in Chapters 2380, 6400 and 6500; the incident management process in the proposed §§ 6100.401—6100.405; the quality management process in the proposed § 6100.45 (relating to quality management) and the individual plan process in the proposed §§ 6100.221—6100.224. The IRRC asks if the duties in § 6100.52(b)(2)(ii) and (iii) are beyond the scope of the rights team. The IRRC asks if the rights team members have the skills to resolve certain behaviors that may be directly linked to a particular disability. The IRRC asks if the rights team must meet every 3 months if there are no incidents. Other commentators object to a team meeting every 3 months stating that less frequent or more frequent team reviews may be necessary. Several commentators suggest reviews every 6 months. A county government states that it has an internal rights team that meets eight times per quarter to review incidents and study trends. Another county government states that the team must be independent and conflict free, rather than directed by a provider who may be self-serving. A provider association, plus numerous form letters from commentators, suggest that an individual be included as a member of the rights team on a case-by-case basis. The IRRC asks to explain the need for and reasonableness of this section.

Response

The Department agrees the proposed sections are not necessary or reasonable as drafted and they are deleted; relevant sections are revised and relocated to §§ 6100.344 (relating to human rights team) and 6100.345 (relating to behavior support component of the individual plan). Similar changes are made in applicable sections of the final-form regulation for Chapters 2380, 2390, 6400 and 6500. While the concept of a comprehensive and objective team of professionals to review and analyze rights violations and the use of restraints was developed and supported in concept by the work group, creating and regulating such a comprehensive team through regulatory chapters that apply only to providers of services is not practical. The concept of an individual, person-centered team and that of a broad-based team of objective professionals completing a systemic analysis were confused, creating a team that was duplicative and impractical.

The review and analysis of rights violations are appropriately governed by §§ 2380.19, 2390.19(d)-(h), 6100.405, 6400.20 and 6500.22 relating to incident analysis.

As suggested by numerous commentators, the Department retains and extends the current licensing requirements in §§ 2380.154, 6400.194 and 6500.164 (relating to human rights team) to Chapters 2390 and 6100 regarding the review of the use of restraints and restrictive procedures. See §§ 2380.154, 2390.174, 6100.344, 6400.194, and 6500.164.

The broad-based systemic review of potential rights issues and restraint use will be addressed by the county human rights committees, required as part of the county mental health and intellectual disability programs operating agreements, rather than through this chapter that applies to providers.

In response to the comments from the IRRC and others about the frequency of the team meetings, § 6100.345 requires the behavior support component of the individual plan to be reviewed and revised as necessary by the human rights team, according to the time frame established by the team, not to exceed 6 months between reviews. This allows the team to establish a review schedule based on the needs of the individual.

§ 6100.53—Conflict of interest

The IRRC asks if a person serving on a governing body who is a friend or family member of an individual must disclose the relationship. An advocacy organization asks to retain the specificity in current § 51.33 (relating to conflict of interest). A provider association, plus numerous form letters from commentators, ask to delete subsection (b) for clarity. An advocacy organization, a family member, a provider association and a provider support individuals and families serving on governing boards.

Response

A friend or relative of an individual does not need to disclose the person's relationship with the individual in order to preserve the confidentiality of the relationship. The Department supports the inclusion of individuals, friends and relatives on the governing body board to provide practical guidance and a real life experience and perspective to the board's deliberations.

A change is made to subsection (a) to delete the review and approval by the provider's full governing board, since not all provider agencies have a governing board and because the final-form regulation does not generally require approval of provider policies by the board. Subsection (b) is retained; the provider must comply with its own conflict of interest policy. In subsection (c), "if applicable" is added, since there may be no governing board.

§ 6100.54—Recordkeeping

The IRRC asks how and where the records in subsection (d) will be maintained. A few provider associations, plus numerous form letters from commentators, ask to clarify that electronic records are permissible. A county government asks to clarify where the records go when a provider closes. A few providers state that this section is redundant of the Health Insurance Portability and Accountability Act (HIPAA). A provider association, plus numerous form letters from commentators, ask to assure compliance with HIPAA regarding release of records to government entities. A provider states that this section conflicts with HIPAA. A provider asks to clarify that disability rights advocates and CMS have access to provider records. Several providers support the 4-year retention requirement as reasonable.

Response

No substantive change is made to this section. The Department does not regulate where or in what format the records are kept to allow flexibility for the provider to establish and maintain an effective and efficient recordkeeping system. Electronic records are permitted. Records must be made available for service provision and for review by the Department and other authorized monitoring agencies, but the record location and record format are intentionally not specified.

In response to the question about where records go when a provider closes, § 6100.307 (relating to transfer of records) is applicable.

This section complies with HIPAA. In accordance with HIPAA, health care oversight agencies, including government licensing and monitoring agencies and the Federally-authorized Disability Rights Pennsylvania, have full and immediate access to individual records. No permission or authorization is required. See disclosure as required by law at 45 CFR § 164.512(a) (relating to uses

and disclosures required by law); disclosure to the Department at 62 P.S. § 1016; disclosure to Disability Rights Pennsylvania at 42 U.S.C.A. § 15043; and disclosure to health oversight agency at 45 CFR § 164.512(d) (relating to uses and disclosures for which an authorization or opportunity to agree or object is not required).

§ 6100.55—Reserved capacity

A few families and providers support the right of an individual to return home after hospital or therapeutic leave. A provider association asks to add medical leave. A provider states that it is costly to fund vacancies. A few provider associations, plus numerous form letters from commentators, and an advocacy organization support the concept to return home, but ask that sufficient funds be provided to hold a vacancy. The commentators ask how the provider will be paid for days when an individual is absent. A commentator asks that partial reimbursement be provided when an individual is absent.

Response

The Department made significant changes to this section to address the commentators' concerns. The changes to approved program capacity allow for an adjustment to the provider's rate for the time period of the individual's extended medical, hospital or therapeutic leave. This rate adjustment allows an individual to return home, while providing appropriate compensation to the provider. This revision was shared with the work group in March 2017 for review and comment; the response from the work group was favorable.

In addition, medical leave is added to hospital and therapeutic leave under subsection (b).

§ 6100.81—HCBS provider requirements

A provider association notes that a license from the Department of Health is rarely required. Another provider association is reluctant to support the provision for the Department's pre-enrollment training since the training course is unknown. A provider asks the Department to complete a timely review of enrollment documents. A few county governments ask if a currently sanctioned provider can be enrolled or if a provider with previous sanctions can be enrolled.

Response

In subsection (a), the Department revised the language to clarify that the provider shall meet the qualifications for each HCBS the provider intends to provide. This is a language form change, and not a substantive change.

In subsections (b)(4) and (c), while rare, a health care facility license, such as a home health care agency license, may be required. The reference to a particular department is changed to reference the applicable State licensure agency.

The Department's pre-enrollment training program is designed to assure that the applicant is knowledgeable and aware of the provider requirements. The Department's pre-enrollment training program has been utilized since March 2016; providers across Pennsylvania are familiar with this training program.

The Department is committed to performing a timely review; however, applicants are strongly encouraged to submit a full, error-free and complete application package to provide for a timely review and approval process.

In response to the comment asking to clarify whether a currently sanctioned provider can be enrolled or if a provider with previous sanctions can be enrolled, § 6100.81(d) is revised to delete

the automatic disenrollment; rather, the Department may deny provider enrollment if the Department has issued a sanction under §§ 6100.741—6100.744. See § 6100.743 (relating to consideration as to type of sanction utilized) for the criteria the Department will use to determine whether provider enrollment will be denied or if other sanctions will be applied.

§ 6100.82—HCBS enrollment documentation (HCBS documentation in proposed rulemaking)

A provider association asks to include the right to a willing and qualified provider and that there is no individual cost limit in Pennsylvania. Another provider association, plus numerous form letters from commentators, ask to combine §§ 6100.81 and 6100.82. A few county governments ask to retitle this section as qualification documentation.

Response

In this section, the term "operate" is corrected to "provide." The citation in § 6100.82(7) is changed to encompass applicable statutes and regulations. The right to a willing and qualified provider is addressed in § 6100.182 (relating to rights of the individual). The Department did not combine the two sections since shorter and distinct sections are easier to read. In addition, the Department changed the title of the section to "HCBS enrollment documentation" to accurately reflect the provisions of this section.

The Department did not include language on the lack of an individual cost limit because the cost limit relates to the HCBS waiver application and the comparison of HCBS waiver costs to institutional services. It is a function of the Department's HCBS waiver application to and approval from the Federal government and not a matter to be regulated by a State requirement.

§ 6100.85—Ongoing HCBS provider qualifications in proposed rulemaking

A provider association, plus numerous form letters from commentators, ask that this section be consistent with State law regarding the applicability and enforcement of departmental policies and procedures through the adoption of regulations and that subsection (b) be consistent with the 5-year waiver renewal. Another provider association, plus numerous form letters from commentators, ask the Department to specify the frequency of the intervals in subsection (b). A few county governments ask that the requirements in subsection (d) apply to all staff persons, including fiscal staff persons, and not just those who come into contact with an individual. An advocacy organization and a few providers ask to clarify the system of award management and to restrict employment and access to any person on this list.

Response

This section is deleted entirely because it is unnecessary to state these requirements in this chapter. The medical assistance provider application process under §§ 1101.41—1101.43 (relating to participation) applies.

§ 6100.85 (§ 6100.86 in proposed rulemaking)—Delivery of HCBS

A provider association, plus numerous form letters from commentators, ask to clarify that this section does not limit a provider's ability to conduct private-pay business and that the provisions apply only to HCBS and base-funding. The same provider association asks if the reference to the individual plan in the proposed subsection (d) refers to the whole plan, including staffing ratios and the frequency and duration of services. Another provider association asks to delete this subsection as unnecessary.

Response

As previously stated, in response to questions about the Department's authority to enforce the Federal waivers through incorporation by reference in the regulation, the Department decided to delete such references throughout Chapter 6100. Therefore, proposed subsection (b) is deleted. In response to the private-pay comment, as stated in § 6100.2 (relating to applicability), this chapter applies to HCBS and base-funding and does not apply to privately-funded programs, services and placements. The requirement to deliver the services specified in the individual plan in subsection (c) applies to the entire plan.

Subsection (d) (proposed subsection (c)) is necessary for the Department to monitor and enforce that HCBS are delivered in accordance with the service needs authorized in the individual plans and to ensure health and safety protections for individuals.

§§ 2380.37, 2390.40, 6100.141, 6400.50 and 6500.48—Training records (Annual training plan at §§ 2380.37, 2390.40, 6100.141, 6400.50 and 6500.46 in proposed rulemaking)

Several commentators support the latitude given to providers to design their own training plan. Numerous comments from providers and provider associations object to the proposed annual training plan as overly prescriptive. Comments from a university, an individual, a family and a few providers support the requirement for an annual training plan. The IRRC questions the feasibility and reasonableness of the annual training plan and how the plan protects the health, safety and well-being of the individuals who receive services.

Response

The proposed concept of the annual training plan was developed by the work group in response to concerns that mandated training should require a few core courses for all staff positions, with special topics provided based upon the staff person's job duties and experience. The annual training plan was intended as the provider's self-designed blueprint to plan, organize and deliver comprehensive and purposeful staff training for the upcoming year, while specifying only four core courses related to person-centered practices, incident management, individual rights and abuse prevention and reporting to be provided to all staff. In response to public comments, the proposed requirement for an annual training plan is deleted. The Department encourages providers to assess staff training needs on an annual basis, plan the targeted training courses well in advance of the training dates and acquire or provide the targeted training at appropriate intervals.

With the deletion of the annual training plan, the phrase "related to job skills and knowledge" is added to the annual training requirements at § 6100.143(a) (relating to annual training) to clarify what is counted as part of annual training hours.

§§ 2380.38—2380.39, 2390.48—2390.49, 6100.142—6100.143, 6400.51—6400.52 and 6500.46—6500.47—Orientation and annual training

Numerous comments were received on the topic of orientation and annual training. Public comments on the proposed orientation and annual training requirements vary widely. The IRRC asks the Department to explain how the orientation and annual training requirements relate to all services, provider types and service delivery models, as well as the need for and reasonableness of the training requirements. Several commentators, including a provider association, plus numerous form letters from commentators, applaud the Department for making the training requirements uniform and compatible across all types of licensed facilities, HCBS funding and base-funding.

A commentator objects to the training and certification requirements as they are cost prohibitive and unrealistic given the amount of industry turnover in direct care staff. The same commentator also states the changes imply a professional level of education and there is no evidence to support these added costs are compensated by the rates.

Several commentators cite an increased cost to provide and attend the training as the reason they object to the orientation and annual training. Several providers ask the Department to develop and offer the core training courses, free of charge. A family group asks that training be provided face-to-face, if possible.

Numerous commentators, including providers, county governments, advocacy organizations, families and individuals, support the applicability of the four core courses across the full range of staff positions, including ancillary positions such as maintenance, clerical, administrative, housekeeping, dietary, management and fiscal staff positions, while numerous providers suggest that the training audience be reduced to only those staff positions that provide direct service to individuals.

Numerous commentators support the requirement to provide training for all consultants, interns, volunteers and household members with no exceptions, while others ask to exempt all or some consultants, interns, volunteers or household members. An advocacy organization supports the proposed training exemption for natural supports.

Numerous commentators support the four core training courses, while others ask to add or delete a core course. Some suggest requiring training only in abuse prevention or community relationships. Some ask to require training in the individual plan, cultural competency, emergency management, provider billing, Everyday Lives and employment. A family organization and a group of individuals ask to require training in positive interventions as one of the core courses required for all staff.

Several commentators ask to exempt consultants and clinicians who are professionally licensed. The IRRC asks if consultants must complete the required orientation for each provider with whom they contract or if the training is portable.

Numerous commentators support the annual training hours as proposed with 24 hours for direct care staff and 12 hours for ancillary staff. Several commentators applaud the reduction in training hours for the chief executive officer from 24 hours annually as specified in current §§ 2380.36(b), 2390.40(b) and 6400.46(c) (relating to staff training) to 12 hours annually. Several commentators ask for reduced hours for part-time direct service staff. A provider association and numerous form letters from commentators ask that the specification for 8 hours of training in the core courses in the proposed § 6100.143(c) be deleted. A provider asks to reduce the hours in § 6100.143(c) from 8 to 4 hours.

A provider association, plus numerous form letters from commentators, ask to specify how long training records must be kept.

A provider association asks to require no annual training for life sharers and to consider the unintended employer relationship and consequences for Internal Revenue Service implications. The same provider association contends that requiring training for life sharers supports a medical model.

Response

The Department values the discussion and diversity of opinions relating to the mandated minimum orientation and annual training requirements within the HCBS, base-funding and licensing service systems. The Department agrees with the commentators who support the uniform and compatible training requirements across all types of licensed facilities, HCBS funding and base-funding. The uniform training requirements are of great benefit to both providers and individuals. The individual benefits by receiving services from staff who receive consistent training. The provider benefits through the Department's design and offering of universal core courses that encompass all of its staff and by having trained staff who may seamlessly transfer to other services and facilities within its own operations. The training consolidation and uniformity across services will result in reduced training costs as staff may transfer from one service to another within the

same provider organization with no added training costs. The core training courses relating to person-centered approaches, rights, abuse and incidents are portable and as such will transfer from one provider to another, thus reducing training costs for new hires transferring across provider agencies.

Certain training requirements do not apply to special program types, based upon the needs of the individuals who receive services in the specific program. The training requirements that do not apply for an agency with choice include the number of annual training hours in § 6100.143 (relating to annual training), the training course in § 6100.143(c)(5) and the requirements for training in §§ 6100.141—6100.143 (relating to training records; orientation; and annual training) for staff persons who work fewer than 30 days in a 12-month period. See § 6100.802(b)(3) (relating to agency with choice). The training requirements in §§ 6100.141—6100.143 do not apply for an organized health care delivery system and vendor goods and services. See §§ 6100.804(b)(2) and 6100.806(b)(5) (relating to organized health care delivery system; and vendor goods and services).

The cost for staff training is included in the fee schedule rates. Further, the final-form regulation does not address or increase the education or certification requirements for direct service professionals.

The Department has developed and will offer online training courses free of charge related to the required core training topics specified in §§ 2380.38—2380.39, 2390.48—2390.49, 6100.142—6100.143, 6400.51—6400.52 and 6500.46—6500.47. While use of the departmental courses is optional, these courses meet the requirements of the regulations, while saving training development costs for providers. The courses may be provided face-to-face or through online teaching and testing. Many providers will experience no increase in training costs as they already provide incident management, abuse reporting and other value-based training to all staff, including ancillary staff; however, for those providers who do not currently train ancillary staff, the fee schedule rates provide sufficient HCBS reimbursement for the training of all staff positions. The core courses are required for all staff even if a staff person does not interact directly with an individual. For example, ancillary staff may overhear an incident of abuse over the telephone, observe possible theft while reviewing the individual's finances or hear a threat to an individual through an open window while landscaping.

The training requirements are reasonable because in the course of employment a staff person serving in any position may encounter an individual who receives services; the staff person must understand how to interact appropriately with the individual. While a staff person may not have direct contact with an individual, the staff person requires a basic level of training on the required topics, since the staff person may be in a position of decision-making or implementation related to the physical location where services are delivered or about the financial or administrative polices or procedures.

As specified in §§ 2380.39, 2390.49, 6100.143, 6400.52 and 6500.47, annual training can be provided on the job as part of the staff person's scheduled work day, through supervisory conferences, staff meetings or training provided for individuals and staff persons at the same time. For an ancillary position, an average of 1 hour of training must be provided each month, which can be provided on the job. For instance, an office staff person may complete an online course on the agency's new word processing software, a fiscal staff person may complete an online course on the agency's required accounting methods, a maintenance staff person may be taught the OSHA rules for safe use of a new lawn care machine by a supervisor or a dietary staff person may watch and learn new cooking techniques or recipes from a televised cooking show. Staff in all positions and at all experience levels benefit from learning about their specific jobs as well as about the services provided to the individuals by the provider agency. These requirements adequately protect the public health and safety by providing the core training elements for the provision of services within the HCBS system and allowing the provider to customize the training content to specifically address the needs of the individuals who receive services and the staff person's specific job duties.

Based on public comments, two courses have been added in § 6100.143(c)(5) and (6), and in the related four licensing chapters, as core courses required as part of annual training for direct service positions. All staff who work directly with individuals must complete training on the safe and appropriate use of behavior supports, as well as the implementation of the individual plan for the individuals for whom services are provided. Basic competency relating to the appropriate use of behavior supports by direct service professionals is critical to protect the health and safety of the individuals with an intellectual disability or autism across all service types, provider types and service delivery methods. All individuals who receive services have an individual plan that identifies the need for services and supports, the services and supports to be provided and the expected outcomes. Each direct service professional must be familiar with the individual plan for the individual for whom they provide services. Requiring annual training ensures that each direct service professional receives at least the minimum level of training on the updates and revisions to the individual plan.

In response to recommendations by the work group, ancillary staff who are employed or contracted by a building owner who is not the provider are exempt from training. In response to comments and recommendations by the work group, consultants who provide an HCBS for fewer than 30 days within a 12-month period and who are professionally licensed, registered or certified in the health care or social services fields by the Department of State are exempt from training. Training hours completed by licensed, registered or certified health care or social service professionals as part of their license, registration or certificate requirements count toward their annual training. Household members who do not provide a reimbursed service are exempt from training.

A volunteer who works alone with individuals must complete the training; however, "volunteer" is defined as a person who does not receive compensation, but who provides a service through an organization or provider that recruits, plans and organizes duties and assignments. A volunteer is an organized and scheduled component of the service and support system. A volunteer does not include a person who provides intermittent and ancillary assistance, such as sweeping the floors or playing the piano. A volunteer does not include an individual's friends or relatives, unless they work as part of an organized volunteer program. This new definition will exclude the occasional and unplanned assistance from a community member who wishes to contribute occasional and unscheduled time. Volunteers who are never alone with individuals do not require training since they do not have the responsibility to report abuse or incidents, and they will be under the watchful eye of trained staff.

In response to public comments, the requirement in §§ 2380.39, 2390.49, 6100.143, 6400.52 and 6500.47 for 8 hours of the annual training hours to be provided in the core courses is deleted. While all staff must complete training in the core areas annually, the provider may determine the scope and length of the training necessary based upon the staff position and the staff experience level. For example, a direct care professional who has been employed for 2 years may complete 2 hours on abuse prevention and reporting, while a fiscal staff person may complete only 15 minutes on the same subject. The provider may tailor and adapt the core training topics to the needs of each staff position.

Proposed § 6100.144 (relating to natural supports) is deleted. This chapter does not apply to persons who provide a support, defined as an unpaid activity or assistance provided to an individual that is not planned or arranged by a provider.

In response to the question about the length of record retention, see § 6100.54 (relating to recordkeeping) that requires records to be kept for 4 years from the fiscal year end, until audits and litigation are resolved and in accordance with Federal and State statutes and regulations; this section applies to all records of the provider, including training records.

Annual training is critical for life sharers who provide services in an occasionally isolated setting with little day-to-day oversight. The life sharer must know the duties to report abuse and incidents,

as well as person-centered approaches and individual rights. Further, none of the required training areas are health-care related. The training requirements may be factored into contracts with life sharers.

The specific reference to "household members" is deleted since household members are direct service professionals if they provide an HCBS.

§§ 2380.21, 2390.21, 6100.181, 6400.31 and 6500.31—Individual rights; Client rights; Exercise of rights

A group of individuals, a family organization and a county government applaud the expansion of rights and the alignment with the CMS regulation in 42 CFR §§ 441.300—441.310 and fully support the rights as proposed. A group of individuals ask to add the right to free assembly, the right to complain and the right to seek help from the government. An advocacy organization and a family support the clarification on guardianship. A university and a provider association ask to require the provider to inform individuals about how and to whom to report a violation of rights.

A provider association asks to delete the word "continually" in proposed subsection (b) as it is subjective.

A provider association asks not to duplicate the civil rights survey process completed under licensing.

A county government asks to require a mediation process if there is disagreement between a legal guardian and the provider. A provider asks to delete proposed subsections (e) and (f) since all court orders must be followed. An advocacy organization offers an extensive rewrite of proposed subsections (e)-(g) to clarify the role of the provider to obtain a court order to limit the guardian's participation and to request the guardian to honor the individual's wishes to the greatest extent possible.

Response

The right of an individual to complain is addressed in § 6100.51 (relating to complaints), which affirms the right to file a complaint and also provides a clear process regarding the filing of complaints. While the right to free assembly and to seek help from the government are essential rights, these rights are not specific to the individuals who receive HCBS and require no procedural standards. These rights are afforded to the general public and therefore, are not necessary to specify in the Department's regulations.

In response to comments, proposed subsection (b) is deleted; the requirement to educate, assist and provide the accommodations necessary is added to the new subsection (b); and the conditions of guardianship are clarified in subsection (e). Subsection (e) is retained to provide clarity that court orders must be followed and take precedence over the regulatory requirements regarding the exercise of rights. Subsection (f) is retained for the Department to monitor whether providers are allowing legal guardians to exercise their rights with respect to assisting individuals.

With respect to the request for required mediation, the Department believes that the established processes for individual complaints and the individual planning processes are sufficient safeguards to deal with disputes between a legal guardian and a provider.

No changes will occur relating to the Department's civil rights survey that occurs as part of the licensing application process. While the Department's civil rights survey gathers broad-based compliance data, the on-site licensing inspection measures compliance with civil rights practice as specified in § 6100.182(a) and (b) (relating to rights of the individual).

§§ 2380.21, 2390.21, 6100.182, 6400.32 and 6500.32—Individual rights; Client rights; Rights of the individual

A university and a county government support this section as proposed. A provider association, plus numerous form letters from commentators, and a provider state that subsection (d) regarding dignity and respect is too vague. A family organization asks to add the following to the list of rights: human rights, communication in one's native language, pursuit of romantic relationships, marry the person of choice, have children and seek employment to support themselves. An advocacy organization asks to add the right to auxiliary aids and services. A provider organization asks to add the right to be educated about choices and consequences. A provider association asks to clarify in subsection (e) that the individual's choice may not jeopardize another person's health and safety and a few providers and a family ask how the individual plan section applies to this right.

A provider association, plus numerous form letters from commentators, and a provider ask for health and safety exceptions regarding subsections (f), (g), (h) and (i).

Several commentators ask how subsection (g) regarding the individual's control over his own schedule aligns with the Federal waiver provision regarding the community integration percentage. The IRRC asks how subsection (g) aligns with the Department's proposed plan for services to be in the community 75% of the time and the feasibility of this proposed requirement. A provider association, plus numerous form letters from commentators, agree in concept with subsection (g), but question how it will be applied given the staffing costs.

A university asks to add the right for the individual to lead the development of the individual plan in subsection (n).

Response

In response to the comment regarding the vagueness of subsection (d), requiring that the individual be treated with dignity and respect, the Department has effectively administered this regulatory provision in various departmental licensing regulatory chapters since 1999. See §§ 3800.32(c), 2600.42(c) and 2800.42(c) (relating to specific rights). The words "dignity and respect" are intrinsic to the protections of the health, safety and human rights of the individuals. Dignity and respect are essential factors in how an individual is addressed, how services are provided and how the individual's possessions are managed. In accordance with the *Pennsylvania Code and Bulletin Style Manual, Fifth Edition*, § 2.11 (relating to definition section), a word used in its dictionary meaning may not be defined. This chapter intends no special meaning of the terms "dignity" and "respect." The *Merriam-Webster* dictionary defines "dignity" as "the quality or state of being worthy, honored, or esteemed." The *Merriam-Webster* dictionary defines "respect" as "high or special regard." See Merriam-Webster.com. *Merriam-Webster*, n.d. Web. 29 June 2017.

While the additional rights suggested are valued and important rights, these rights fall under "legal and civil rights" afforded to all citizens as stated in § 6100.182(b). Therefore, the Department did not add additional specific rights.

Subsection (e), regarding the right to make choices, is applied in accordance with § 6100.184(a)-(c) (relating to negotiation of choices), which provides for a procedure to negotiate and resolve differences between individuals.

Subsections (f), (g), (h) and (i) are applied through the modification of rights in accordance with §§ 6100.184(c), 6100.223(9), 6400.33, 6400.185(6), 6500.33 and 6500.155(6) that address the modification of rights by the individual plan team if there is a significant health and safety risk to the individual or others. A new paragraph is added under § 6100.184(c) to address the modification of rights through the individual plan process.

Subsection (g) provides the right for the individual to control the individual's own schedule and activities. This includes the right to choose to attend day programs and employment of the individual's choice. The individual's rights and choices are paramount and take top priority when making plans for services. Subsection (g) is applied in accordance with § 6100.184(a), based upon the individual's choices, staffing and the choices of the group living in the home.

The provision referenced by the IRRC about services provided in the community 75% of the time is not in the proposed rulemaking. There is no integration percentage mandated in this regulation. The proposed Federal waiver provisions included a plan for community integration, which has since been amended based on public comment. The community integration Federal waiver requirement has been reduced from the proposed 75% community integration level to a 25% community integration level. The approved Federal waiver provides that 25% of an individual's services, on an average monthly basis, must be provided outside the licensed facility, effective July 1, 2019. Further, the waiver permits a variance if the individual chooses to spend less time in the community after having been provided with opportunities for community integration.

Subsection (o) is added to align with current §§ 2380.176, 2390.126, 6400.216 and 6500.185.

In response to the comment related to subsection (n), the individual directs the individual plan team in accordance with § 6100.222(a) (relating to the individual plan process).

§§ 6100.183, 6400.32 and 6500.32—Additional rights of the individual in a residential service location; rights of the individual

Regarding § 6100.183(a), the IRRC, a few provider associations, plus numerous form letters from commentators and several providers, ask what happens and who is liable if someone is injured or abused by a visitor and how this regulation protects the health, safety and well-being of the individuals. A provider association and several providers ask to remove the phrase "at any time" as it relates to a visitor. A provider association asks that an individual's rights cannot conflict with the rights of others. A provider supports the rights as proposed and suggests that visitation risks be addressed through the individual planning process. A commentator asks that life sharing be able to set its own family visitation rules. A county government is concerned for vulnerable individuals where there is a reason to suspect that the implementation of rights may be manipulated by the provider. A university supports the residential rights as proposed and suggests that many of the rights in this subsection should be expanded to include day programs.

Regarding § 6100.183(c), a few county governments ask to mandate the right to internet access.

Regarding § 6100.183(d), the IRRC and a provider association, plus numerous form letters from commentators, ask how the right to manage one's own finances is implemented if the individual has a representative payee.

Regarding § 6100.183(e), a family emphasizes that the right to choose with whom to share a bedroom is required by CMS. A provider asks to add the phrase "whenever possible." Another provider asks to remove this right because of the possibility that the individual may change the individual's mind.

A provider asks to assure funding for compliance with § 6100.183(f). A group of commentators support the right of the individuals to decorate their own homes, as some homes look like they were professionally decorated and not where people live. A county government asks that exercising this right not infringe on the rights of other individuals, such as hanging an offensive poster in the common living area.

The IRRC, numerous provider associations, form letters and providers express concern that § 6100.183(g), which permits the locking of a bedroom door, may create a health and safety risk by

restricting staff access in the event of a fire or other emergency. Several providers ask that this right be applied based on an assessment of the individual's medical, intellectual and physical care needs. Several providers ask to require staff to knock before entering a bedroom, but not allow the locking of bedroom doors. A county government and a group of commentators support the right to lock one's own bedroom door to provide for privacy and since this is the individual's own home.

Regarding § 6100.183(i) ((h) in proposed rulemaking), a provider association, plus numerous form letters from commentators and numerous providers, ask how the needs of individuals with Prader Willi syndrome, special diets and allergies will be addressed.

Regarding § 6100.183(j) ((i) in proposed rulemaking), a provider association and a few providers ask that the right to make informed health care decisions apply only if the individual has the cognitive ability to understand the consequences of not following a doctor's orders.

Response

Subsection (a) remains unchanged, with the exception of a minor change to insert clarifying language. The provider is responsible to assure the health, safety and well-being of all individuals; this requires a careful balance of providing freedom of choice, while still protecting the individual and others. The right to receive scheduled and unscheduled visitors has been in place in residential licensing regulations for more than 2 decades. See current §§ 6400.33(g) and 6500.33(g) (relating to rights of the individual). This is a fundamental right of adults in residential living. The application of this regulation for children is governed by § 6100.56 (relating to children's services). Sections 6100.184, 6100.223(9), 6400.33, 6400.185(6), 6500.33 and 6500.155(6) address the modification of rights by the individual plan team if there is a significant health and safety risk to the individual or others. This right applies equally for life sharing homes. The individual plan team includes the individual, persons designated by the individual and the support coordinator to assure that the individual's rights are protected. The rights in subsection (a) are not extended to day programs since these rights relate to residential services.

In response to IRRC's comment regarding provider liability, an individual has the right to make choices and accept risks in accordance with § 6100.182(e) (relating to rights of the individual). The provider is responsible to assess and implement services in a manner that mitigates risks as described in § 6100.222 (relating to individual plan process), § 6100.223 (relating to content of the individual plan) and § 6100.403 (relating to individual needs). In § 6100.184 (relating to negotiation of choices), § 6100.223 and § 6100.345 (relating to behavior support component of the individual plan), situations in which individual rights will require modification to assure health and safety are addressed. Provider liability is evaluated by the provider's adherence to the regulation governing rights and risk mitigation and whether the provider conducted due diligence in developing and implementing risk mitigation strategies.

The final-form regulation protects the public health, safety and well-being, while balancing the rights of the individual to enjoy the same liberties as all Pennsylvania citizens, through the enactment of requirements, including risk management strategies and rights modifications as necessary for the individual's health and safety protection, individual planning, restrictive procedures and behavior support planning and incident reporting and investigation aimed at preventing recurrence. See §§ 6100.182, 6100.222, 6100.223, 6100.345 and 6100.403.

In the event that an individual is abused or injured by a visitor, the procedures for incident reporting and follow-up as specified in §§ 6100.401—6100.405 are required to be followed, including creating a plan to prevent recurrence of the event that may involve restricting the perpetrator's access to the individual. Current regulatory requirements at § 6400.33(g) protect an individual's right to receive scheduled and unscheduled visitors, communicate, associate and meet privately with family and persons of the individual's own choice. The final-form regulation does not create new risks for individuals who receive residential services.

While the right to internet access is not specifically addressed, internet access is included in the term "telecommunications" in subsection (c). Subsection (b) is revised to allow an individual to share the individual's contact information with others at the individual's own choosing.

Regarding subsection (d), if there is a representative payee, the representative payee makes financial decisions on behalf of the individual. An individual's right to manage finances is not absolute where a representative payee is involved in managing finances. In fulfilling these responsibilities, it is expected that the representative payee will take into consideration the individual's wishes, preferences and choices.

No change is made to subsection (e) regarding the sharing of a bedroom. If an individual changes the individual's mind about the individual's choice of a roommate, or for no roommate, the provider must honor the individual's choice. An individual may not be forced to share a room with someone with whom the individual does not wish to share a room. Individual rights are intrinsic to the provision of services and factored into the fee schedule rates.

No change is made to subsection (f) regarding the right to refuse services. Individuals may decorate their own bedrooms and homes at their own expense. Sections 6100.184, 6400.33 and 6500.33 (relating to negotiation of choices) address disagreements regarding décor in the common areas of the home.

Subsection (g) requires the right to privacy in the individual's bedroom by locking the door. This provision aligns with the Federal regulation regarding privacy in sleeping units. See 42 CFR § 441.301(c)(4)(vi)(B) (relating to contents of request for a waiver). The Department appreciates the concern to keep an individual safe regarding the locking of a bedroom door in subsection (g). Proposed § 6100.443 (relating to access to the bedroom and the home) is deleted and the substantive provisions are placed in §§ 6100.183(g) and (h), 6400.32(r) and (s) and 6500.32(r) and (s) to implement the right to lock one's own bedroom door and have a key to one's home. The regulation is reworded as the right to lock one's door, rather than the condition that each door have a lock as proposed in § 6100.443. While this language change is a subtle difference, this change creates a right and choice for an individual, rather than a necessary physical site provision for all individuals. This right may be modified in accordance with §§ 6100.184, 6100.223(9), 6100.345(d) and related sections of Chapters 6400 and 6500, that address the modification of rights by the individual plan team if there is a significant health and safety risk to the individual or others. The ability to modify this right allows each individual circumstance to be taken into consideration, including the need to protect the health, safety and well-being of individuals.

Individuals' privacy rights need to be respected. The provisions in subsection (g)(2) permitting access to the individual's room in the event of an emergency, and in subsection (g)(3) requiring assistive technology to enable the individual to unlock the individual's own door, protect the health, safety and well-being of the individual by permitting emergency egress. See the discussion of the public comments in response to § 6100.443 (relating to access) to the bedroom and the home in proposed rulemaking.

Regarding the right to access food under subsection (i) ((h) in proposed rulemaking), the needs of an individual who has Prader Willi syndrome, a life sustaining special diet or a life threatening allergy are addressed through the modification of rights in accordance with §§ 6100.184, 6100.223(9), 6400.33, 6400.185(6), 6500.33 and 6500.155(6). These sections address the modification of rights by the individual plan team if there is a significant health and safety risk to the individual or others. Rights may be modified only if the medical condition creates a significant and immediate health and safety risk and not for a physician recommended diet such as weight loss or sugar intake. An adult individual has the right, as any other adult without an intellectual disability or autism, to choose not to lose weight, to eat foods that are unhealthy and to eat foods to which the individual is allergic, provided such action does not jeopardize the individual's immediate life safety.

Regarding the right to make informed health care decisions under subsection (j) ((i) in proposed rulemaking), the term "informed" is removed from the final-form regulation, since an individual may make the individual's own health care decisions, unless a court has appointed a legal guardian to make health care decisions on behalf of the individual.

§§ 2380.21, 2390.21, 6100.184, 6400.33 and 6500.33—Individual rights; Client rights; Negotiation of choices

A group of individuals, a few county governments, a few provider associations, plus numerous form letters from commentators, and a few providers support this section as proposed. A university asks that these provisions not permit a loophole for providers to abide by the group's rights to override an individual's rights. A provider and a family ask to explain how the rights section relates to the individual plan section on modification of rights. A group of individuals asks the Department to provide training on this topic. A county government association offers to provide training on the balancing and protection of individual rights. A provider states that rights are not one-size-fits-all and even the freest of men have limits on rights and choices. A provider asks to address the right to take risks. A provider asks not to overstate that rights cannot be violated as this is not true, citing an individual who has Prader Willi syndrome and a medical dietary restriction. A few providers ask to mandate that the support coordinator be involved in the negotiation of choices. A few providers ask to mandate that the individual plan team be involved in the negotiation of an individual's choices. The IRRC and a provider association, plus numerous form letters from commentators, ask the Department to clarify what happens when negotiations fail, who makes the ultimate decision and how regulatory compliance is to be documented.

Response

In response to comments, subsection (c) is added to explain how this section relates to § 6100.223(9) (relating to content of the individual plan). An individual's rights may be modified by the individual plan team only to the extent necessary to mitigate significant health and safety risks to the individual or others. The Department will work with the county government association to provide training to support the balance of rights for all individuals.

The provider has the responsibility to apply subsection (b). The provider develops a procedure to manage the negotiation process, including what happens if negotiations fail. The provider's procedures will determine if and how the support coordinator and the individual plan team will be involved. If there is an unresolved issue at the provider level, the provider may specify in its procedures how issues are resolved. For example, the procedures could specify that an agreement has been reached with the county mental health and intellectual disability and autism office for the county office to serve as the arbitrator, that counsel may be sought from another independent source or that consultation with the various individual plan teams or the support coordinators will occur to resolve the matter. The responsibility to protect the rights of all individuals lies with the provider.

Documentation of the individual plan revisions and notes from the various individual plan meetings and negotiations are required under § 6100.225 (relating to base-funding support coordination, base-funding support coordination and TSM) and will be reviewed to assess regulatory compliance. Interviews with staff persons and individuals may also occur to measure regulatory compliance.

§§ 2380.21, 2390.21, 6100.185, 6400.34 and 6500.34—Individual rights; Client rights; Informing of rights

The IRRC asks if the Department considered requiring providers to inform the individual about how to report when rights are being violated. A group of individuals asks to require notice of rights to be provided monthly, rather than annually.

Response

The requested change to require providers to inform the individual about how to report a rights violation is added at § 6100.185(a). The Department supports the principle that explaining and applying rights is an everyday activity, rather than a formality that occurs once a year; however, the prescribed regulatory mandate remains on an annual basis because it is reasonable for it to occur during the individual plan team meeting.

§ 6100.186—Facilitating personal relationships

The IRRC, a provider association, plus numerous form letters from commentators, and several other commentators are concerned that the proposed language implies that the provider must make all accommodations without acknowledgement of feasibility, reasonableness or economic impact, without addressing what is necessary or when it is necessary. A provider association asks to clarify the family's role in decision-making. Another provider association asks to omit this section as there is too much variance in family dynamics. A provider association and numerous form letters from commentators ask that the nature of family involvement be determined at the individual plan meeting; a provider specifically disagrees with the same provider association and supports the section as proposed. An advocacy organization suggests that this requirement is more appropriate for residential settings. An advocacy organization states that although family involvement is generally a good idea, some individuals do not wish their families be involved; it is important to maintain the designation by the individual as used throughout the proposed rulemaking. A family association acknowledges that while there are some unhealthy family relationships, the core involvement of family should not be threatened by these few unhealthy relationships.

Response

Multiple revisions are made to this section relating to accommodations for visits and activities. Subsections (a) and (b), as amended, are reasonable and feasible requirements for the provider to incorporate into its daily routines and operations and will not result in additional costs beyond the services and activities factored into the fee schedule rates. As amended, subsection (a) requires providers to facilitate and make accommodations to assist an individual. There is no requirement to meet all of a family's demands or special requests, but rather to facilitate and make accommodations to assist the individual to visit with and participate in activities with family or friends. This may mean holding a meeting at a time convenient to the family such as after work hours, inviting the family well in advance of a special holiday party, providing private space for a family visit or helping the individual to make travel plans to visit a friend. Providing accommodations for an individual to spend time with those the individual cares about will provide for a better quality of life, improved independence with reduced reliance on formal HCBS and productive outcomes for daily living.

Subsection (c) is added to clarify that the provider should presume family involvement unless the individual indicates otherwise. The individual's preferences to involve, or not to involve, family must be honored for each activity and for each incidence of potential involvement. The choice to involve, or not to involve, family remains with the individual. This section allows sufficient discretion to honor choices and to address the differences in family dynamics. The individual plan process is one avenue to address significant family involvement issues, but each incident of facilitating relationships is not required to be addressed through the formal individual plan process. While more prevalent in a residential setting, the issue of facilitating relationships applies to both residential and non-residential settings.

§§ 2380.182, 2390.152, 6100.221, 6400.182 and 6500.152—Development, annual update and revision of the individual plan; Development of the individual plan

The IRRC and a provider association, plus numerous form letters from commentators, ask to define the terms "service implementation plan," "support coordinator" and "targeted support coordinator." Several commentators applaud the person-centered planning focus. A family association and a university support the proposed term "individual support plan." A county government asks to add futures planning and to focus on the person rather than the planning process. A provider association, plus numerous form letters from commentators, a family association, a family and a provider support the requirement for one approved and authorized plan.

Response

The term "service implementation plan" is revised to clarify that this is a provider's implementation plan. This term is defined and explained in § 6100.221(g). This term is not used in Chapters 2380, 2390, 6400 or 6500; therefore, no definition is necessary in these chapters.

The terms "support coordination" and "targeted support management" are defined in § 6100.802(a) and (b) (relating to support coordination, targeted support management and base-funding support coordination). These terms are not used in Chapters 2380, 2390, 6400 or 6500; therefore, no definitions are necessary in these chapters. Clarification is added that this section applies to base-funding support coordinators.

The term for "plan" has evolved over the years. In the early 1990s, the term "individual program plan" was used. In the early 2010s, the term was changed to "individual service plan." The proposed rulemaking uses the term "individual support plan" to reflect the supportive nature of the services. The term "individual plan" is used in the final-form regulation to keep the language simple and in plain English. Because the regulation term is only two words, the acronym is no longer used. "Individual plan" is defined in § 6100.3 (relating to definitions).

§ 6100.221(c) (§§ 6100.221(d), 6100.221(e) and 6100.221(f)in proposed rulemaking)—Development of individual plan

The IRRC and several commentators ask why there is no timeline for completion of an assessment in Chapter 6100, what areas are required in the assessment and who is responsible for completing the assessment. The IRRC asks to address the economic and fiscal impact on the regulated community.

The IRRC and several commentators ask why the provision in § 6100.221(c) ((d) in proposed rulemaking), regarding the development of the individual plan prior to the individual receiving a reimbursed service, appears to be inconsistent with the provisions relating to the timing of the individual plan completion in Chapters 2380, 2390, 6400 and 6500.

Response

Assessments are not regulated in Chapter 6100 since the provider is not responsible for completing the assessment. Assessments are completed by an outside agency under contract with the Department. There is no economic or fiscal impact on the regulated community related to completion of an assessment.

The differences in the requirements for the timing of the individual plan completion between the five chapters are based on the varying governing laws and the scope of the chapters. Chapter 6100 governs HCBS for which Federal funding is received, and thus, the Federal regulations apply, including the need for a plan prior to the provision of services. See 42 CFR § 441.301(c)(2)(ix) (relating to contents of request for a waiver). The licensing regulations, including Chapters 2380, 2390, 6400, and 6500, govern licensed facilities that may or may not receive Federal funding; therefore, the timing of the individual plan completion differs. Based on public comment, the timing

of the individual plan completion for the four licensing chapters is revised to reconcile the timing of the assessment and the individual plan. See the discussion under §§ 2380.182, 2390.152, 6400.182 and 6500.152.

§§ 2380.182, 2390.152, 6400.182 and 6500.152—Development, annual update and revision of the individual plan

Several commentators ask to clarify the proposed contradictory timelines for completing the assessment and individual plan in the four chapters of licensing regulations.

Response

Since the assessment must be completed within 60 days of admission in the four licensing chapters, the timeline for completing the individual plan is revised from 60 days to 90 days in subsection (b) to allow 30 days following the completion of the assessment to complete the individual plan.

§§ 2380.182, 2390.152, 6100.221(d), 6400.182 and 6500.152 (§ 6100.221(e) in proposed rulemaking)—Development, annual update and revision of the individual plan; development of the individual plan

The IRRC and an advocacy organization ask that the individual plan be revised annually.

Response

The individual plan must be revised annually; however, since this is a requirement for the support coordinator, this requirement is located in § 6100.225(a). In addition to the requirement to revise the individual plan annually, § 6100.221(d) requires that the individual plan be revised when an individual's needs or service system changes and upon the request of an individual.

§§ 2380.182, 2390.152, 6100.221(e), 6400.182 and 6500.152 (§ 6100.221(f) in proposed rulemaking)—Development, annual update and revision of the individual plan; Development of individual plan

A provider association, plus numerous form letters from commentators, ask to delete this subsection regarding the need for the individual plan to be based on a current assessment. No reason is given for this proposed deletion.

Response

No change is made since this subsection is needed to assure that the individual plan is developed based on current and relevant historical and clinical data.

§§ 2380.182, 2390.152, 6100.221, 6400.182 and 6500.152 (§ 6100.221(h) in proposed rulemaking)—Development, annual update and revision of the individual plan; development of the individual plan

A provider asks to use its own form. Another provider asks to be permitted to request an update to the plan.

Response

The proposed subsection (h) that required an individual plan to be documented on a form specified by the Department is deleted as it is unnecessary.

§ 2390.153(b)—Individual plan team

The IRRC and several commentators ask why a minimum of three persons must attend the team meeting.

Response

The team described in subsection (a) includes approximately seven members representing various disciplines. Requiring a minimum of three team members who are involved in the individual's services or who are knowledgeable about the individual's needs is reasonable and necessary to develop an individual plan that is meaningful. This requirement has been codified in Chapter 2390 since 2010. See 40 Pa.B. 4935; § 2390.154(b) (relating to plan team participation).

§§ 2380.184, 2390.154, 6100.222, 6400.184 and 6500.154—Individual plan process

A provider association and a provider ask to explain "directed by the individual" in subsection (a). A provider association, plus numerous form letters from commentators, ask to remove "maximum" in subsection (b)(4). The IRRC and several commentators ask the Department to explain who is responsible for the individual plan process, how providers will demonstrate compliance with subsection (b)(5) and which guidelines are referenced in subsection (b)(9). A university supports subsection (b)(7) regarding communication in a clear and understandable language. An advocacy organization asks to delete subsection (b)(8), (9) and (10) since the provisions are best practice and non-regulatory. A provider supports the inclusion of subsection (b)(8) relating to cultural considerations. An advocacy organization asks to clarify that if there is a disagreement between the individual and the support coordinator, the support coordinator must provide the service as requested or issue a formal denial with a right of appeal. The same advocacy organization asks to add that the individual need not sign the individual plan until the individual is satisfied with the plan. An advocacy organization asks to require the provision of auxiliary aids and services to ensure effective communication.

Response

Subsection (a) is revised to clarify that the individual directs the plan to the extent possible and as desired by the individual.

Subsection (b)(2), (3) and (4) is clarified to use active voice and to reflect changes in other sections of the final-form regulation relating to persons designated by the individual.

The term "maximum" is deleted from subsection (b)(4).

The support coordinator is responsible to plan, schedule and direct the individual plan process as specified in § 6100.225 (relating to support coordination, base-funding support coordination and TSM).

Compliance with subsection (b)(5) will be measured by interviewing the individual and other individual plan members. No paper documentation is necessary. The proposed term "informed" is deleted because it is unnecessary.

The guidelines in subsection (b)(9) are the support coordination agency's procedures to resolve disagreements.

Subsection (b)(8), (9) and (10) is retained as appropriate individual protections; however, (b)(11) is deleted as unnecessary.

An individual maintains the right to appeal the individual plan in accordance with 55 Pa. Code § 275.1 (relating to policy), whether the individual signs or does not sign the individual plan.

§§ 2380.185, 2390.155, 6100.223, 6400.185 and 6500.155—Content of the individual plan

Several county governments, a county association, a family organization and an advocacy organization ask to reduce the length of the individual plan, relocating many of the requirements to a record section. A group of individuals and a university support the full comprehensive individual plan. A provider association, plus numerous form letters from commentators, state that the individual plan content is rigid and conflicts with the Everyday Lives goal of simplifying the plan. Commentators ask to add to the content the following items: assessment for self-administration of medications, family relationship map, family medical history, the individual's lifetime medical history, medical diagnoses, management of personal funds, need for behavior support and housing goals. Commentators ask to delete proposed paragraphs (10), (11), (12), (14), (15), (16), (17), (18), (19) and (21). The IRRC and several commentators ask to clarify how proposed paragraph (11) supports the concept of person-centered planning. Several commentators request that employment not be required for all individuals, particularly seniors and children. The IRRC, a university and a provider association, plus numerous form letters from commentators, ask to delete or explain the reasonableness and need for proposed paragraph (17). The work group, several providers and an advocacy organization ask to address and permit electronic signatures in paragraph (21). Several commentators ask to reorder the paragraphs.

Response

Many changes are made to this section to reduce the volume and complexity of the individual plan and relocate multiple items, such as health care information, choice of provider and financial information in proposed paragraphs (15), (16) and (18) of § 6100.225(c). No new items are added to the content of the plan because they are unnecessary.

In response to the comment on the individual plan content being rigid and conflicting with the Everyday Lives goal, the Department believes the content areas identified in the regulation provide necessary information to establish preferences, desired outcomes and necessary services and supports for necessary health and safety protections for individuals.

The requirement relating to employment in § 6100.223(7) (§ 6100.223(11) in proposed rulemaking), is revised to apply only to those individuals of employment age, to exclude children and seniors who do not wish to work. The term "active pursuit of" is also deleted from this paragraph; however, "competitive integrated employment as a first priority" is maintained because the requirement supports the concept of person-centered approaches by providing opportunities for each individual to be employed in an integrated work environment, based on the aptitudes, needs and choices of the individual. The content of the individual plan also is reduced for the four licensing chapters because some of the facilities licensed under Chapters 2380, 2390, 6400 and 6500 are not funded through the ODP service system and some licensed facilities do not provide services to individuals with an intellectual disability or autism.

Proposed paragraph (20) regarding the person responsible to monitor the plan is deleted as unnecessary. The signatures in proposed paragraph (21) are no longer required on the individual plan; rather, the list of persons who attended the plan meeting are documented in the record in § 6100.225(c).

Paragraphs (8) and (9) ((13) and (14) in proposed rulemaking) are revised to coincide with changes made to § 6100.184(c) (relating to negotiation of choices) and § 6100.348 (relating to physical restraint).

§ 6100.225—Support coordination, base-funding support coordination and TSM

A provider association, plus numerous form letters from commentators, express appreciation for the removal of the individual plan timelines specified in the current regulations. A few county governments ask to add that the support coordinator must monitor individual services at the frequency required by the Department.

Response

No substantive change is made. The frequency of support coordination monitoring is not governed by this chapter; rather, the frequency of support coordination monitoring is addressed in the Federal waivers.

Subsection (c) is added to address individual record requirements moved from the content of the individual plan in § 6100.223 (relating to content of the individual plan).

No additions are made to Chapters 2380, 2390, 6400 and 6500 since individual record requirements are adequately addressed in §§ 2380.173, 2390.124, 6400.213 and 6500.182.

§ 6100.226—Documentation of claims

The IRRC and numerous commentators ask to simplify, clarify and reduce the paperwork required to document a medical assistance claim for service delivery. A provider association asks for a standard claim form. The IRRC and numerous commentators ask if documentation is required each time a service is delivered, including whether documentation relates to amount, frequency and duration or to units. Several providers state that daily documentation disrupts services. The IRRC asks how this section applies to group living.

A provider association, plus numerous form letters from commentators and a few other providers, ask to delete subsections (c), (d), (e) and (f) as unnecessary and overly prescriptive.

In proposed subsection (f), the IRRC asks to clarify from what date the 3-month review is determined. Several commentators ask to explain the difference between a claim and a progress note. A few county governments ask to require monthly progress notes. An advocacy organization and a few providers support 3-month progress notes.

Response

This section applies to residential services (commonly referred to as group living) as well as day program services.

Section 6100.226 is substantially revised and a new § 6100.227 (relating to progress notes) is added to address the public comments. The question about whether documentation is required each time a service is delivered, including whether the documentation relates to the amount, frequency and duration or to units is addressed in § 6100.226 (relating to documentation of claims). In response to comments received, the Department added § 6100.226(b)(1)-(3) that specifies how to document a claim. The Department standardized the documentation required to submit an HCBS claim. As requested by commentators, § 6100.226 distinguishes claim documentation from progress notes in § 6100.227. Section 6100.227(a) addresses the question about the date from which the 3-month review begins; the 3-month review begins on the date of the initial claim related to the individual.

§ 6100.261—Access to the community

The IRRC notes that the term "ongoing" in subsection (b) is subjective and asks that the Department define or delete the term. In subsection (c), the IRRC and a provider association, plus

numerous form letters from commentators, ask how providers will determine the degree of community access and what standards the regulated community is expected to meet.

Response

Proposed subsections (b) and (c) are deleted as unnecessary.

§ 6100.262—Employment

A provider association, plus numerous form letters from commentators, ask to delete subsection (a), the reference to the individual plan in subsection (c) and support coordinator responsibilities in subsection (d). A few advocacy organizations, a provider and a provider association ask to exempt seniors and children from the work requirements. A university supports this requirement for employment first. An advocacy organization and a provider association ask to delete subsection (b) as this causes unnecessary delays. Other commentators suggest that the regulation should permit the right to not work, require that the individual be given information about employment, require that employment be specified in the individual plan and require the support coordinator to provide information regarding the Office of Vocational Rehabilitation.

Response

Subsection (a) is clarified to provide information about employment options that are appropriate to the individual to address the concerns regarding seniors and children who are not of employment age. Proposed subsections (b), (c) and (d) are deleted. To further clarify, a definition of "competitive integrated employment" is added.

§ 6100.263—Education in proposed rulemaking

A few commentators ask to explain the financial limits to provide this service, clarify what is meant by life-long learning, clarify who is responsible to provide these services, require access to education regardless of whether an individual has a high school diploma and provide information about education opportunities. A university supports this requirement as proposed.

Response

While the Department supports the opportunity for educational opportunities for all individuals, this section is deleted as unnecessary and beyond the funding available through the ODP service system.

§ 6100.301—Individual choice

A university asks to change the title of this center heading to "change of support providers," add the right to choose and add information regarding where and how to report if this right is violated. A provider asks to relabel this center heading as "transition to a new provider." A provider association, plus numerous form letters from commentators, ask to relabel this center heading as "transition of services." A provider association, plus numerous form letters from commentators and another provider, ask to clarify that this section applies to a change of a support coordinator as well as a direct service provider. A few county governments support this role for the support coordinator.

Response

The title of this center heading is changed to "Transition To A New Provider" to clarify that the transition relates to the provider. Minor edits are made to this section to enhance clarity. This section applies to a support coordination organization as well as a direct service provider. Additional reporting requirements are unnecessary and individuals have a right to choose a provider as set forth in § 6100.182(j) (relating to rights of the individual).

§ 6100.302—Cooperation during individual transition

A university supports this section as proposed. An advocacy organization asks to require an individual plan meeting prior to a transition. A provider asks that these functions be the role of the support coordinator. A provider association, plus numerous form letters from commentators and several other providers, support that transportation should be a shared responsibility arranged by the current and the potential new provider and that it is essential that the providers cooperate with each other. A provider association, plus numerous form letters from commentators and another provider, state that it is not the current provider's responsibility to arrange for transportation to find or visit other service locations.

Response

The title of this section is changed to "Cooperation during individual transition" to better capture the intent of this section.

An individual plan meeting is not always required prior to a transition because of ongoing discussions and working relationships amongst the involved parties. The support coordinator is involved, but is not responsible to arrange and provide transportation to visit other service locations. The Department agrees that the visits to other service locations are a shared responsibility between the current and the new provider, as stated in subsection (a). It is the provider's responsibility to assist the individual to find and visit other service locations.

§ 6100.303—Involuntary transfer or change of provider (Reasons for a transfer or change in a provider in proposed rulemaking)

An advocacy organization asks that an individual should never have to move due to insufficient funds. A county government asks to delete the phrase "with the provision of supplemental support" in subsection (a)(2). A university asks to omit subsection (a)(3) as a reason for involuntary discharge, stating that the ADA requires physical accommodations. A few provider associations, plus numerous form letters from commentators and several providers, request that the following reasons for involuntary discharge be added in subsection (a): irreconcilable disagreement with families or individuals, insufficient funds, natural disasters, staff changes, situations beyond a provider's control, provider liability, stress, intimidation of others, danger to self or others, service location closure, hospitalization and abuse. A county government and a family association ask to state that discharge may not occur due to hospitalization, illness or therapeutic leave. A provider requests the ability to anonymously refuse service. A provider association asks to change the term "retaliation" to "response" in subsection (b).

Response

The title of this section is changed to "Involuntary transfer or change of provider" to better capture the intent of this section. Insufficient funds is not a permitted reason for involuntary discharge in subsection (a). The phrase "with the provision of supplemental support" in subsection (a)(2) is retained; this means that an individual may not be discharged due to a change in needs without the provider first attempting to provide supplemental services. Subsection (a)(4) is added to address the commentators' concerns that a closure of a service location, such as in response to a natural disaster, is also a legitimate reason for the individual to transfer. The other reasons suggested as allowable reasons for involuntary discharge such as family disagreements, staff changes and hospitalization are not appropriate bases for involuntary discharge. Discharge may not occur due to illness or during medical, hospital or therapeutic leave. The Department is unsure of the intent of the comment requesting the ability to deny a service anonymously. The term "retaliation" is changed to "response" in subsection (b) as suggested and "filing a grievance" is changed to "filing a complaint" to conform to the changes made to § 6100.51.

§ 6100.304—Written notice

A provider asks why an individual must provide notice of a transition. A provider association, plus numerous form letters from commentators, support the requirement in proposed subsection (a) for the individual to provide at least 30 days' notice of departure. A provider association and a provider ask that not all individual team members be involved in the transition. Another provider association asks to identify which team member provides the notice.

In proposed subsection (b), the IRRC and numerous providers ask to allow transitions to occur sooner if agreed to by both parties and to account for emergencies where the individual's or another's immediate health and safety may be at risk. A provider asks that written notice be addressed through the individual plan meetings. A provider asks to change 45 days' notice to only 10 days' notice. A provider association, plus numerous form letters from commentators, ask to change 45 days' notice to 30 days' notice. A county government supports the 45 days' notice. An advocacy organization asks to change the 45 days' notice to 90 days' notice. A family association asks that the family be informed of all transitions.

Response

The proposed subsection (a) is deleted since the individual has the right to leave a service or facility at any time without notice. The provider may encourage, but not require, that notice of departure be provided.

The time frame in subsection (a) ((b) in proposed rulemaking) remains at 45 days for provider notification to allow sufficient time for the individual and others to prepare for transition and select a new and appropriate service location. The family is notified of the transition in accordance with subsection (a)(2) ((b)(2) in proposed rulemaking) if the individual wishes that the family be notified.

Final-form subsection (b) is added to allow for a transfer earlier than the 45 days to protect the health and safety of the individual or others.

§ 6100.305—Continuation of service

A provider association, plus numerous form letters from commentators, ask that a time limit be established as to how long the provider must support the individual, require the Department to act quickly and to specify the process for obtaining departmental approval. Another provider association states that this is detrimental to housemates if a willing provider is not found timely. Another provider association, plus numerous form letters from commentators, state that there are cases where additional resources will be required to continue services and that an avenue to bill the Department should be provided. A provider supports this section, stating that the current provider must maintain HCBS to assure safety and a smooth transition. A few providers ask for the ability to immediately suspend service. A provider is concerned that the necessary staffing may not be available.

Response

Approval by the Department is deleted as the continuity of service is generally managed by the designated managing entity and the support coordinator, rather than the Department. No other changes are made to this section in order to protect the health and safety of the individual during transition. The residential fee schedule rates include adequate funding to cover the cost of added staffing and services during the transition period.

§ 6100.306—Transition planning

A provider association, plus numerous form letters from commentators, ask to delete this section since this is addressed in § 6100.302 (relating to cooperation during individual transition). A provider requests specification about the use of equipment and dietary needs to ensure health and safety.

Response

This section is not duplicative of § 6100.302. Section 6100.302 addresses the cooperation between the current and new providers. This section addresses the role of the support coordinator in planning the transition meetings. The needs of the individual, including the use of equipment and dietary needs, must be addressed during the transition period. See § 6100.305 (relating to continuation of service).

§ 6100.307—Transfer of records

A provider association, plus numerous form letters from commentators, ask that the individual be required to give a signed release to transfer the records and to address HIPAA confidentiality provisions in sharing records from one provider to another. The same provider association asks how much of the record must be transferred. A family asks that the record copies be provided without cost. A provider association, plus numerous form letters from commentators, ask to delete this section and combine the provisions with § 6100.302.

Response

Disclosure of health care information for purposes of case management and care coordination is considered treatment, payment or health care operations for which specific authorization is not required. See 45 CFR § 164.506 (relating to uses and disclosures to carry out treatment, payment, or health care operations). There is no HIPAA violation in transferring records from the current to the new provider. In response to the question of how much of the record must be transferred, the term "complete" is added to subsection (a). There is no cost to the individual for the record transfer between providers.

This section is not duplicative of § 6100.302. Section 6100.302 addresses the cooperation between the current and new providers during transition. This section addresses the transfer of records following transition.

§§ 2380.151—2380.160; 2390.171—2390.180; 6100.341—6100.350; 6400.191—6400.200 and 6500.161—6500.170—Restrictive procedures (positive intervention in proposed rulemaking)

Several commentators ask to retitle this section as "behavioral intervention," "positive behavior supports" or "safe behavior management." Several commentators support the title as "positive intervention."

General comments relating to proposed § 6100.52 (relating to rights team) suggest that the basic provisions regarding the use of restraints and restrictive procedures in current §§ 2380.151—2380.165, 6400.191—6400.206 and 6500.161—6500.176 be retained.

General comments on restrictive procedures include enthusiastic support for limiting restraints to only emergency health and safety situations, support for the move to a restraint-free environment, reinforcing acceptable behaviors, a desire to rewrite this entire section by a clinician, support for behavior intervention with the use of core teams and requesting the same restrictive procedure provisions across all four licensing chapters and Chapter 6100.

Response

The title of this center heading is changed to "Restrictive Procedures" to best describe the content of the sections.

The Department reconsiders its approach to this section and concurs with commentators who suggest the retention of §§ 2380.151—2380.165, 6400.191—6400.206 and 6500.161—6500.176 as the underpinning for this section on restrictive procedures, and further applying the same provisions to Chapters 2390 and 6100 to provide continuity of health and safety protections and continuity of services across the intellectual disability and autism service system. Many sections and principles relating to restrictive procedures in the licensing regulations for community homes, life sharing homes and adult training facilities are retained, updated and transferred to Chapters 2390 and 6100.

The Department appreciates and acknowledges the overwhelming support from individuals, county governments, providers, families, advocates and universities to move toward a restraint-free environment. While the regulations set the minimum standards for the prohibitions of restraints, and require protections for the use of restrictive procedures, it is the intellectual disability and autism community as a whole moving forward with shared values and principles that will continue to make a difference to reduce the use of harmful acts and controlling practices that take away an individual's freedom, pride and dignity through the use of restraints and harmful restrictive procedures.

The Department has carefully reviewed all comments regarding the use of restraints and restrictive procedures, and the Department's clinicians and other behavior health experts have been consulted and have advised relating to best practices on the use of restraints and restrictive procedures. The final-form regulation conforms to the experts' recommendations.

§§ 2380.151, 2390.171, 6100.341, 6400.191 and 6500.161—Definition of restrictive procedures (Use of a positive intervention in proposed rulemaking)

Numerous commentators object to the proposed term "dangerous behavior" as used to determine the circumstances under which a physical restraint may be used.

Response

The term "dangerous behavior" is deleted throughout the regulation. The term "restrictive procedure" and the corresponding definitions in the current §§ 2380.151, 6400.191 and 6500.161 (relating to definition of restrictive procedures) are maintained and adopted in §§ 2390.171 and 6100.341 (relating to definition of restrictive procedures).

§§ 2380.152, 2390.172, 6100.342, 6400.192 and 6500.162—Written policy

The requirement for the provider to develop and implement a written policy describing the use of restrictive procedures as contained in the current §§ 2380.152, 6400.192 and 6500.162 (relating to written policy) is maintained and adopted in §§ 2390.172 and 6100.342 (relating to written policy).

§§ 2380.153, 2390.173, 6100.343, 6400.193 and 6500.163—Appropriate use of restrictive procedures

A county government asks to strike the reference to reinforcing appropriate behavior as this is a concept of applied behavior analysis and can be a stimulus to increase the likelihood of a behavior. A provider suggests that a clinician be consulted, rather than requiring the use of the least intrusive method. A provider suggests that behavior plans for individuals with autism often include restrictive procedures and restraints as part of the treatment program.

Response

The overarching parameters for the use of restrictive procedures as contained in the current §§ 2380.153, 6400.193 and 6500.163 (relating to appropriate use of restrictive procedures) are maintained and adopted in §§ 2390.173 and 6100.343 (relating to appropriate use of restrictive procedures; appropriate use of a restrictive procedure). The term "reinforcing appropriate behavior" is no longer used based on the concerns raised regarding applied behavior analysis by the county government. A clinician may not override the fundamental principle of applying the least restrictive method necessary to achieve the desired behavior. The use of physical restraints and restrictive procedures is not an acceptable part of the treatment plan for individuals with autism unless a behavior support clinical team has reviewed and approved the entire plan. Restraints prohibited by this final-form regulation are not permitted for use on an individual with autism.

§§ 2380.154, 2390.174, 6100.344, 6400.194 and 6500.164—Human rights team

As discussed in this preamble in §§ 2380.156, 2390.176, 6100.52, 6400.196 and 6500.166—Rights team in proposed rulemaking, numerous commentators representing families, universities, advocacy organizations, county governments, providers and a few provider associations, plus numerous form letters from commentators, object to all or a portion of the proposed § 6100.52 (relating to rights team). The IRRC and other commentators state that the proposed role of the rights team overlaps and duplicates the roles and procedures of the restrictive procedure process in Chapters 2380, 6400 and 6500.

A university, a provider association and an advocacy organization suggest that the individual plan team is not qualified to write the behavior support component of an individual plan. A university suggests that a functional behavior analyst should write the behavior support component of the plan.

Response

As suggested by numerous commentators, the Department retains, adapts and extends the current licensing requirements in current §§ 2380.154, 6400.194 and 6500.164 (relating to restrictive procedure review committee) to Chapters 2390 and 6100 regarding the review of the use of restraints and restrictive procedures. The new §§ 2380.154, 2390.174, 6100.344, 6400.194, and 6500.164 carry forward the current licensing requirements for a team with a majority of persons who do not provide direct services to the individual and require a record of the team meetings to be kept. In response to comments about the qualifications of the individual plan team, and the comment suggesting that a functional behavior analyst write the behavior support component of the plan, a new requirement is added to require the human rights team to include a behavior specialist who was not involved in the development of the behavior support component of the plan. This requirement is consistent with the current licensing regulations requiring "other professionals, as appropriate" to participate on the team. See §§ 2380.155(b), 6400.195(b) and 6500.165(b) (relating to restrictive procedure plan). The qualifications of the behavior specialist are intentionally broad to permit an array of professionals to serve in this capacity. The concept of a behavior specialist was shared with the work group in March 2017 and there were no objections.

§§ 2380.155, 2390.175, 6100.345, 6400.195 and 6500.165—Behavior support component of the individual plan (§ 6100.342 (relating to PSP) in proposed rulemaking)

A university supports the behavior support component as part of the individual plan. A provider association, plus numerous form letters from commentators, ask to require a baseline of the behavior being addressed in the plan. A provider asks if this plan replaces the crisis behavior plan. A provider association, plus numerous form letters from commentators, ask to delete the term "functional analysis." A provider association and several providers ask to use the term "functional assessment." The IRRC asks to define "functional analysis," clarify who is responsible for completing the functional analysis and explain how these requirements will be implemented. A provider asks to require speech therapy services. An advocacy organization asks to require necessary auxiliary aids and services.

Response

This section is revised to maintain and apply the current §§ 2380.155, 6400.195 and 6500.165 (relating to restrictive procedure plan) in Chapters 2390 and 6100. The current requirements, including the plan, the review of the plan at least every 6 months and the content of the plan, are similar to the current Chapter 2380, 6400 and 6500 requirements. Subsection (d) is added to § 6100.345, consistent with current §§ 2380.155(b), 6400.195(b) and 6500.165(b) which require the participation of other appropriate professionals in the development of the behavior support component of the individual plan (the licensing chapters refer to this plan as the "restrictive procedure plan"). The term "functional analysis" has been replaced with "an assessment of the behavior, including the suspected reason for the behavior" in response to public comment. As specified in subsection (a), the human rights team reviews and approves the behavior support component of the individual plan prior to the use of a restrictive procedure.

Subsection (d) addresses who must develop the behavior support component of the individual plan if a physical restraint is used, or if a restrictive procedure is used to modify an individual's rights in accordance with § 6100.223(9) (relating to content of the individual plan). Neither current regulation nor the proposed rulemaking references a crisis behavior plan. The behavior support component of the plan at times includes a crisis plan section. The behavior support component of the individual plan is implemented by the provider in accordance with the individual plan.

With respect to the comments on requiring speech therapy services and auxiliary aids and services, each individual plan process governs how these services are identified and authorized. It is unnecessary to address these services in the behavior support component of the individual plan.

§§ 2380.156, 2390.176, 6100.346, 6400.196 and 6500.166—Staff training

A family association asks that persons applying a restraint be properly trained. A provider association, plus numerous form letters from commentators, ask to clarify the content of staff training.

Response

The requirements in current §§ 2380.156(b), (c) and (d); 6400.196(b), (c) and (d); and 6500.166(b), (c) and (d) are retained and adopted in §§ 2390.176 and 6100.346 (relating to staff training). The requirements in current §§ 2380.156(a), 6400.196(a) and 6500.166(a) regard- ing training in the use of behavior supports are addressed in the final-form §§ 2380.39(c)(5), 2390.49(c)(5), 6100.143(c)(5), 6400.52(c)(5) and 6500.47(b)(5).

§§ 2380.157, 2390.177, 6100.347, 6400.197 and 6500.167—Prohibited procedures (§ 6100.343 (relating to prohibition of restraints) in proposed rulemaking)

A group of individuals, a university, an advocacy organization, a county government and several providers support the restraint prohibitions as proposed. A provider association, plus numerous form letters from commentators, ask to allow bite release techniques in paragraph (3). A provider association, plus numerous form letters from commentators and several providers, ask to allow helmets to prevent self-injury and wheelchair belts for positioning in paragraph (5). A provider association and a few providers ask to allow post-surgical care and casts for healing in paragraph (5). A provider asks under what circumstances bedrails are allowed in paragraph (5). Another provider asks if geriatric chairs are allowed in paragraph (5). A provider asks to remove the qualifier "as long as the individual can safely remove the device" in paragraph (5). The IRRC and several providers ask for an exclusion for doctor-prescribed mechanical restraints in paragraph (5). Several providers ask to permit the initial 3-month use of mechanical restraints in paragraph (5).

Response

The Department agrees with the commentators who support the movement to reduce and eliminate the use of restraints through the use of alternative positive interventions and appropriate behavior supports.

Paragraph (1) is revised, consistent with current §§ 2380.157, 6400.197 and 6500.167 (relating to seclusion), to clarify that use of a foot pressure lock or holding a door shut is prohibited.

Paragraph (3) is revised to clarify that a clinically-accepted bite release technique is permitted.

Paragraph (4) is revised, consistent with §§ 2380.159, 6400.199 and 6500.169 (relating to chemical restraints), to clarify that an ongoing program of medication and medication prescribed for a stressful event are permitted.

Paragraph (5) is revised to clarify that the following procedures are permitted: a seat belt during movement or transportation, post-surgical and wound care, and a device used for balance or positioning if the device is removed upon the request of the individual and if there is periodic relief from the device. This paragraph also clarifies that a device used for protection during a seizure is permitted if the device is removed upon request of the individual and if there is periodic relief from the device. The ability to remove a device and to provide periodic relief from the device is critical to provide health and safety protection for the individual.

Paragraph (5) is revised to clarify that a bedrail that restricts the movement or function of an individual is prohibited. As proposed, use of a geriatric chair is prohibited.

Paragraph (5) does not permit a health care practitioner to override the individual health and safety protections of this section. A health care practitioner may not be properly educated, or may hold different beliefs on the physical and psychological short-term and long-term risks to an individual. The protection from the use of unauthorized restraint as specified in the final-form regulation is absolute. Regulatory waivers are not permitted regarding this section.

Paragraph (5) does not permit the initial 3-month use of a mechanical restraint because the risk to the individual during the use of a mechanical restraint is significant, the use of a mechanical restraint is cruel and inhumane and alternative positive interventions and behavior supports are effective alternatives to restraint.

The proposed requirements related to physical restraint are relocated to §§ 2380.158, 2390.178, 6100.348, 6400.198 and 6500.168.

§§ 2380.158, 2390.178, 6100.348, 6400.198 and 6500.168—Physical restraint (§ 6100.344 (relating to permitted interventions) in proposed rulemaking)

A university, an advocacy organization and a family support the proposed limitations on physical restraints. A provider association, plus numerous form letters from commentators and another provider, ask to clarify the terms "physical restraint" and "manual restraint." A provider association, plus numerous form letters from commentators, ask to permit verbal redirection and prompts. A provider association and several providers support the reduction from 30 minutes to 15 minutes for use of a physical restraint. Another provider association, plus numerous form letters from commentators, ask to clarify that a physical restraint may not be used for more than 15 minutes in any 2-hour period. A county government and a provider suggest that a physical restraint be permitted for 30 minutes in a 2-hour period to support individuals with difficult behaviors and to protect other individuals and staff. A provider suggests allowing a physical restraint for no more than 15 minutes consecutively and no more than 30 minutes in a 2-hour period. A provider asks to allow waivers for the use of physical restraints. The IRRC and several commentators suggest that proposed § 6100.345(c) and (g) are redundant.

Response

The term "manual restraint" is not used in the final-form regulation. The term "physical restraint" is used and is defined in subsection (a).

Verbal redirection and physical prompts are specifically permitted in subsection (b).

The time period for use of a physical restraint is increased from 15 minutes to 30 minutes consistent with current §§ 2380.161, 6400.202 and 6500.172 (relating to manual restraints). As suggested, the final-form regulation clarifies that the 30-minute time period applies cumulatively within a 2-hour period.

The protection from the use of unauthorized restraint as specified in the final-form regulation is absolute. Regulatory waivers of this section are not permitted. Proposed § 6100.344(c) and (g) are redundant and are deleted.

§§ 2380.159, 2390.179, 6100.349, 6400.199 and 6500.169-—Emergency use of a physical restraint

A few providers ask to allow the use of physical restraints in emergency situations.

Response

A section is added to permit the use of a physical restraint in an unanticipated, emergency basis, not to exceed twice in a 6-month period. This requirement is the same as the current §§ 2380.163, 6400.204 and 6500.174 (relating to emergency use of exclusion and manual restraints).

§§ 2380.160, 2390.180, 6100.350, 6400.200 and 6500.170—Access to or the use of an individual's personal property; Access to or the use of a client's personal property

A few provider associations, plus numerous form letters from commentators, state that there are individuals who understand the consequences of making restitution for damages and the individual plan should allow for this. Another provider asks to collect a security deposit to pay for damages. Another provider raises the legal obligation of an agreement. A county government, a family and several providers ask to require restitution for damages so an individual can understand consequences of actions. A provider association, plus numerous form letters from commentators, suggest that payment be made only if there is a legal order to make restitution and that the representative payee must consent. Yet another provider states that this provision conflicts with the lease requirement. A few advocacy organizations object to the consent provision as it is difficult to view any consent as knowing and voluntary. Other providers ask that the support coordinator or the individual plan team witness the consent.

Response

The provision is not about understanding or teaching the consequences of one's action, but rather the illegality of taking a person's money without consent. Consent may be provided by the individual or the individual's representative payee in the presence of and with the assistance of the support coordinator.

A revision is made to subsection (b) to clarify that the provisions apply if there is no court-ordered restitution. If there is a court-ordered restitution, the court order applies.

§§ 2380.17, 2390.18, 6100.401, 6400.18 and 6500.20—Incident report and investigation; Types of incidents and timelines for reporting

A university supports the broad application of the incident management provisions across all five chapters. A provider association, plus numerous form letters from commentators, ask to remove the

incident provisions from the regulations and instead issue policy. An advocacy organization asks that all providers of HCBS, including all paid household members and life sharers, be required to report incidents. A county government asks that this section apply to person and family directed services.

The IRRC and several commentators ask to explain the difference between alleged and suspected incidents.

The IRRC, several providers and a provider association, plus numerous form letters from commentators, suggest allowing 72 hours to report medication errors and the use of restraints. A provider supports the 24-hour reporting timeline for all incidents.

A provider supports the proposed list of incidents. The IRRC asks why the list of incidents is significantly expanded, the reasonableness of the expanded list and the fiscal and economic impact of such expansion. A few providers ask to clarify the meaning of a suicide attempt. A county government and a provider ask if a psychiatric hospitalization or a hospital observation with no admission is reportable. A county government and a few providers ask to delete the requirement to report emergency room visits. A county government asks if abuse to an individual by another individual is reportable. A few providers ask to clarify that a missing individual is one who is missing for more than 24 hours or in jeopardy if missing for any period of time. A few providers ask not to report the closure of a facility as no investigation is required. A provider association, plus numerous form letters from commentators, ask not to report over-the-counter medication errors. A provider asks to delete all medication errors. An advocacy organization and a family ask to report only significant medication errors. Numerous providers and county governments ask to delete a critical event as this is covered by other categories.

A provider asks that reports be submitted on the victim as well as the perpetrator of the abuse. A provider asks that this section apply only while the individual is under the supervision of the provider and not while home with family or on leave.

A county government asks that all incident reports be submitted through the Department's online information management system, rather than by paper.

In subsection (c) ((b) in proposed rulemaking), the IRRC asks why an individual must be sent a report if the incident relates to the individual and to ensure the notice requirements are clear and reasonable. The IRRC, a provider association, plus numerous form letters from commentators, ask to clarify "immediately report;" the provider association suggests a 2, 4 or 6 hour reporting timeline.

In subsection (e) ((d) in proposed rulemaking), numerous commentators, including county governments and providers, ask to permit an abbreviated notice to protect confidentiality. An advocacy organization commends the Department for making incident notices available to individuals and their designees. A few providers ask not to release incident reports to individuals and families.

Response

Incident management procedures are promulgated as regulation rather than policy to provide the basis for the Department's measurement and enforcement of the requirements.

The Department did not make any change to the release of incident reports to individuals and family members. Individuals and others designated by individuals are permitted to have access to records pertaining to HCBS, including incident reports. Protections are in place to allow for appropriate redaction of such records to protect the privacy of other individuals receiving HCBS.

An "alleged" incident is a situation when a person has stated that an incident occurred, but the evidence has not yet been confirmed to verify that an incident did occur. A "suspected" incident is a situation where there has been no direct observation or evidence of an incident, but someone has a suspicion that an incident occurred.

All incidents, whether they occurred, are alleged to have occurred or if there is a suspicion of such occurrence, must be reported in accordance with the timelines in the final-form regulation. These terms are not defined in the final-form regulation as the dictionary definitions apply.

The change to the reporting timeline for restraints and medication errors is made.

The list of incidents to be reported in § 6100.401 (relating to types of incidents and timelines for reporting) is consistent with the statement of policy codified at §§ 6000.921—6000.923 (relating to incident management). This statement of policy has been in effect since 2004. The list of incidents is not expanded, and in fact, emergency room visits and certain types of medication errors have been eliminated from the list of incidents to be reported.

"Suicide attempt" is clarified to mean "a physical act to complete suicide." An "inpatient psychiatric hospitalization" is an inpatient admission to a hospital, and therefore is reportable. A hospital observation for which there is no admission is not reportable. An emergency room visit is deleted from the list of reportable incidents. "Abuse" is clarified to include abuse to an individual by another individual; this practice of considering abuse to an individual by another individual as abuse has been in place for years within the Department. "Missing individual" is clarified as suggested. Law enforcement activity and fire are clarified to narrow the reporting parameters. An emergency closure of a facility is reportable to provide notice to the Department, counties, the designated managing entity and others. The types of medication errors to be reported are narrowed to require reports only for medications ordered by a health care practitioner, rather than routine over-the-counter medications. The requirement to report a "critical event" is deleted.

An incident report does not necessarily apply to one individual; rather, the incident may be facility-wide, such as a fire or closure, or it may relate to multiple individuals. Incidents must be reported while the individual is under the supervision of the provider and not while on medical, hospital or therapeutic leave.

All incident reporting under Chapter 6100 occurs through the Department's online information management system; however, since some facilities governed by Chapters 2380, 2390, 6400 and 6500 are not funded by the Department through the ODP service system and do not have access to the online reporting system, paper reports are allowed for the four licensing chapters.

In subsection (c), an incident report may be submitted relating to the individual for which the individual or the individual's designated person is unaware; for example, the financial staff discovers a theft of individual funds for which the individual has no knowledge or a visitor reports a potential violation of individual rights for which the individual is unaware. A copy of the incident report does not need to be provided to the individual or to the person designated by the individual if the individual is already aware of the incident. The term "immediately" is revised to "within 24 hours of discovery of an incident relating to the individual."

In subsection (e), a revision is made to allow the submission of a summary of the incident, rather than the actual report.

§§ 2380.17, 2390.18, 6100.402, 6400.18 and 6500.20—Incident report and investigation; Incident investigation

The IRRC and numerous commentators object to the proposed rulemaking requiring that a certified investigator investigate each incident; rather, they ask to report only certain more serious

incidents, citing an extreme administrative burden. A provider association, plus numerous form letters from commentators, ask that abuse to an individual by another individual be investigated by a certified investigator only if there is a serious injury.

An advocacy organization asks to require the use of auxiliary aids to communicate between the individual and the investigator.

An adult day training facility asks to clarify that forms may be submitted by paper for adult training facilities.

Response

Subsection (c) is revised to specify the more serious types of incidents that require investigation by a certified investigator. All cases of abuse must be investigated by a certified investigator, including all cases of abuse to an individual by another individual, to discover and remedy the underlying cause of the abuse.

Communication aids and devices must be used if necessary in accordance with § 6100.50 (relating to communication).

In accordance with final-form § 2380.17(b), incident report forms may be submitted by paper for adult training facilities.

§§ 2380.18, 2390.19, 6100.403, 6400.19 and 6500.21—Incident procedures to protect the individual; Incident procedures to protect the client; Individual needs

A provider association, plus numerous form letters from commentators, ask to omit the support coordinator from subsection (c) relating to revision of the individual plan if indicated by the incident as the support coordinator is on the individual plan team.

Response

This change is made.

§§ 2380.17, 2390.18, 6100.404, 6400.18 and 6500.20—Incident report and investigation; Final incident report

A provider association, plus numerous form letters from commentators, ask to allow an extension if needed for collection of evidence, such as witness statements, police investigation results or lab results.

Response

This change is made.

Subsections (b)(3) and (b)(4) are reordered for clarity. Final-form subsection (b)(4) is revised to address the need to prevent the recurrence of the incident.

§§ 2380.19, 2390.19, 6100.405, 6400.20 and 6500.22—Incident analysis; Incident procedures to protect the client

A county government supports the requirement for incident analysis. A provider association, plus numerous form letters from commentators, ask that incident analysis be the responsibility of the individual plan team. A provider association, plus numerous form letters from commentators and a few other commentators, object to the root cause analysis in subsection (a)(1). A provider association, plus numerous form letters from commentators, state that the corrective action in

subsection (a)(2) is not always necessary. The IRRC and several providers object to the 3-month review in subsection (b), stating that this is a four-fold increase in the current annual review. The IRRC asks if this review is duplicative of the quality management process. A provider asks to change "analyze" to "monitor" in subsection (e). A provider association, plus numerous form letters from commentators, ask to delete "continuously" in subsection (e).

Several adult training facilities and vocational facilities suggest that the incident analysis is duplicative of the incident review process and the civil rights review process that is required through licensing. The same facilities state that the incident analysis is already done by the certified investigator. The same commentators suggest that 3 months is too frequent for incident analysis. An adult training facility states that it is challenging to determine the likelihood of recurrence. An adult day training facility asks that the list of incidents be the same across all five chapters.

Response

Incident analysis is a core function of the provider agency. The provider analyzes all incidents from a broad-based systemic perspective to determine whether there are patterns or trends within the organization.

In subsection (a), "root cause" is changed to "cause" and "corrective action" is modified by "if indicated." In subsection (e), "analyze" is changed to "monitor" and "continuously" is deleted.

This final-form regulation is not a four-fold increase in incident analysis and no new costs are associated with this section. Section 6000.984 (relating to provider incident management quarterly reports) requires a 3-month incident review; this statement of policy has been in effect since 2004. With the substantive changes to § 6100.45 (relating to quality management), there is no redundancy with the incident analysis process.

Regarding the comments by the adult day training and vocational facilities, the incident analysis is a systemic review of all incidents that occurred over the past 3 months to determine if a facility-wide action may be appropriate. This analysis is not duplicative of either the civil rights review that measures compliance with applicable civil rights laws or the certified investigator review that examines the circumstances of a particular, singular incident. Section 6000.984 requires a 3-month incident review; this statement of policy has been in effect for all ODP-funded adult training facilities since 2004. The list of reportable incidents is the same across all five chapters in the final-form regulation.

§ 6100.441—Request for and approval of changes

A provider asks the Department to issue a decision in 24 hours. A provider association, plus numerous form letters from commentators, ask to allow rapid placement through an expedited approval process. A provider association, plus numerous form letters from commentators, ask to clarify the difference between program and licensed capacity. A provider asks to allow excess capacity such as in respite care.

Response

This section is modified to apply to all types of service locations. The term "setting" is changed to "service location" to align with the term "service" as defined in this chapter and the *Merriam-Webster* dictionary definition of "location." See Merriam-Webster.com. *Merriam-Webster*, n.d. Web. 28 June 2017.

The Department, through its regional offices, will continue to respond rapidly to emergency requests to change program capacity. To expedite the Department's approval, a provider should use

the Department's required form, complete all portions of the form clearly and in detail and submit it to the Regional ODP, noting that it is an emergency request.

Program capacity is the number of individuals who may occupy a service location for the purposes of Department funding for the ODP service system. Licensed capacity is the maximum number of individuals who receive services at any one time in accordance with the facility's license under Chapters 2380, 2390, 6400 or 6500. Neither program capacity nor licensed capacity may be exceeded for respite care.

§ 6100.442—Physical accessibility

A county government supports the alignment with the CMS regulation in 42 CFR §§ 441.300—441.310. A university supports the accommodation and the assistive equipment provision. An advocacy organization states that this does not go far enough to ensure physical accessibility; the association asks to train all staff in the use of mobility equipment, assure the equipment is repaired timely and require a loaned device while the equipment is being repaired. A provider association, plus numerous form letters from commentators, state that this requirement causes a provider to incur significant and non-recognized costs. Another provider association, plus numerous form letters from commentators, ask that this section be qualified as only those accommodations that are reasonable and listed in the individual plan.

Response

No change is made to this section. Accessibility accommodations are governed by the ADA.

Maintenance of mobility equipment is appropriately specified in subsection (b).

§ 6100.443—Access to the bedroom and the home in proposed rulemaking

A county association, a university and a county government support this proposed requirement; they ask to determine applicability through the individual plan team. A few providers ask to apply this section based on the individual plan team. A provider association, plus numerous form letters from commentators, ask to revise this section based on the CMS regulation in 42 CFR §§ 441.300—441.310. The IRRC and numerous commentators ask how the proposed requirements will be implemented in the context of health and safety; they ask to explain "appropriate persons" and "authorized persons" as to who has access and how express permission is obtained for each instance of access to the bedroom. A provider association, plus numerous form letters from commentators, express concern regarding the fire safety risk if an individual locks the individual's door; an exception is requested for safety if an individual cannot open the lock; the association believes that kind, caring staff will assure privacy without door locks. The same provider association asks for staff access to provide personal care, in the event of a fire and to prevent hoarding and illegal activity. The same provider association believes locks make the facility more institutional and less homelike. Several providers ask that staff responsible for care have keys to provide emergency access in the case of a fire or medical emergency and to meet care needs. A few providers support locks on bedroom doors, but not locks to the house; they are concerned of the safety risk if the key is lost. Another provider disagrees and supports keys to the entrance to the home, but not to the bedrooms.

Response

This section is deleted and the substantive content is relocated to § 6100.183(g) (relating to additional rights of the individual in a residential service location). The language is revised to provide the right to lock a bedroom door, rather than the express requirement to require a lock on each bedroom door.

The individual plan team will address modification of this right in accordance with § 6100.223(9) (relating to content of the individual plan) if there is a significant health and safety risk.

If the individual cannot open a standard lock, the provider must offer and provide an alternative locking system appropriate for the individual, such as an electronic card, key pad, touch pad, motion detector or voice command.

An individual has the right to lock and unlock the individual's bedroom door and the door to the home. This practice and right to lock a door to provide privacy of person and possessions is consistent with the rights that all citizens have in their own homes. Access by staff is permitted in an emergency, such as a fire, and with express permission by the individual. In instances where an individual's health and safety may be compromised, the individual plan team may design and implement a rights modification in accordance with § 6100.184 (relating to negotiation of choices) and § 6100.223.

The terms "appropriate" and "authorized" are removed; clarification is added that a direct service professional who provides services to an individual should have keys.

§ 6100.444—Lease or ownership in proposed rulemaking

A group of individuals and a university support the lease provision as proposed. The IRRC and numerous commentators question the terms "lease," "landlord" and "tenant" as these terms may trigger undesired consequences regarding tax law, legal proceedings, zoning restrictions, eviction, binding contracts and security deposits. A provider association, plus numerous form letters from commentators, ask the Department to develop a model lease. Another provider association, plus numerous form letters from commentators, ask to use the standard room and board agreement in place of the lease. A few providers ask to exempt life sharing homes from this requirement.

Response

This section is deleted. The room and board residency agreement in § 6100.687 (relating to completing and signing the room and board residency agreement) will be used in place of the lease.

§ 6100.443 (§ 6100.445 in proposed rulemaking)—Integration

The IRRC and a few commentators ask to explain how the same degree of community access and choice will be applied and measured. A provider asks for a health and safety exemption. A university supports this section.

Response

No substantive change is made. The Commonwealth is mandated to meet this Federal regulation to continue to be eligible for $1.8 billion in Federal waiver funds. See 42 CFR §§ 441.301(c)(4)(i) and 441.310 (relating to home and community-based services waiver requirements).

§ 6100.444 (§ 6100.446 in proposed rulemaking)—Size of service location

The IRRC and an advocacy organization state that program quality cannot and should not be defined by the number of persons served. The IRRC asks to explain the reasonableness, the need to limit the number of persons served and the economic impact of this regulation. A university, a group of individuals and a family association strongly support the proposed regulation and ask that large congregate care settings be phased out in a purposeful manner, proposing the date of 2025 to impose the size restrictions on both new and existing day and residential programs. The same groups ask to require downsizing with annual decreases immediately until the size of 4 for residential programs and 15 for day programs is reached for all service locations. An advocacy organization supports the

proposed size limits, but asks that a relocation maintaining the current capacity not be allowed. A county government supports the proposed size limits for new service locations, allowing existing service locations to continue to operate at their current size. A provider believes it is illegal for the Department to control private space. Another provider states this is a positive change. A provider association, plus numerous form letters from commentators, state that the CMS does not impose size limits and that consideration must be given to the additional staff, facility costs and workforce shortages. Another provider association, plus numerous form letters from commentators, express concern that funding will not keep up with the capacity reductions. A third provider association is unsure if size limits are legal and believes that any limit is arbitrary. A few providers ask to delete all size caps, but rather regulate size through the Federal waivers.

Regarding subsection (a), a university comments that existing homes with more than four individuals should be required to downsize. Regarding subsection (b), a university and a family group support the size limit of four for newly funded residential service locations. An advocacy organization generally supports the residential capacity of four, but requests that side-by-side living with eight individuals be permitted to provide choice and independence with minimal support. A provider asks to limit size to 8 to permit economies of scale, stating that Virginia allows 12 individuals in a residential setting. A provider asks to set the residential size limit at six. A provider asks to consider the cost of transportation and the hardship on families. Several providers question if their current four-by-four or eight-by-eight side-by-side residential units are permitted to continue to operate.

Regarding subsection (c), the IRRC states that commentators assert that limiting newly funded day facilities will dramatically increase the cost per unit/per individual. The IRRC asks if the Department considered making a distinction between program licensing roster capacity and daily attendance. A legislator objects to the size of 15 for day programs as the size limit is a one-size-fits-all approach that severely affects cost effectiveness, makes it impossible for providers to open new programs, limits options for consumers and ignores the diversity of the State regarding rural, suburban and urban areas. A university asks to change the effective date for the day program size limit to the effective date of the regulations, rather than the Federal deadline of March 2019. An advocacy organization asks to cease funding of all licensed day programs effective July 2017 to support community participation and Everyday Lives. A provider asserts that no program can make money with a size limit of 15. Another provider asks that a size limit of 15 be imposed effective July 1, 2017. A provider asks to apply the size requirement based on the number of individuals who receive services at any one time. A provider asks to limit the size to 30 to maximize the staffing ratios in Chapters 2380 and 2390. Another provider states that the size limit will force the development of more sites and create pick up and drop off scheduling issues. A provider association, plus numerous form letters from commentators, and several providers assert that the size limit of 15 is arbitrary and insufficient to sustain a service location, that this eliminates choice of program and that the size of 15 does not coincide with the staffing ratios in Chapters 2380 and 2390 at 1:6 and 1:15. The same provider association asks to allow legacy programs to relocate and maintain their size after March 2019.

Response

The Department respects, appreciates and values the comments relating to the quality of life experienced in small homelike, community integrated settings, as well as the desire to provide options for an individual to choose the services that best meet the individual's needs. The vast diversity of opinions and beliefs surrounding the size of service locations is acknowledged and embraced as part of the ever-growing and evolving intellectual disability and autism service system. The final-form regulation strikes a balance of the desires by the advocacy community for enhanced community integration and the economic and choice concerns of the providers.

Regarding subsection (a)(1), existing side-by-side residential units operating in accordance with the Federal waivers and licensing regulations are permitted to continue to operate. Regulatory

waivers may be considered for existing, unique side-by-side settings.

In subsection (c), the size limit for new day programs that are newly funded on or after March 17, 2019 is increased to 25 individuals. This subsection clarifies that the size limit applies liberally based on the number of individuals present in the service location at any one time, rather than by program capacity or licensed capacity. For example, by alternating schedules and by providing community integration activities in small groups for part of the day, a service location may serve a total of 100 individuals, with only 25 individuals present in the service location at any one time. Proposed subsection (c)(2) is deleted as unnecessary due to the revision of subsection (c).

The Department did not make changes to the March 2019 effective date for the program size limits because the Department worked with stakeholders in determining to comply with the Federal government deadline. The Department and many stakeholders believe that the March 2019 effective date is reasonable.

The costs to operate smaller settings, including transportation and staffing costs, are included in the fee schedule rates. Through increased community opportunities, such as active involvement with local activities and clubs, job coaching to teach employment skills, competitive employment opportunities and educational activities, individuals will feel greater pride, self-worth and acceptance, enhancing the individual's quality of life. As community integration increases, the community at large will become more accepting of people with disabilities.

Research on service location size demonstrates that size does impact multiple quality of life dimensions and outcomes. The National Council on Disability's 2015 report "Home and Community-Based Services: Creating Systems for Success at Home, at Work and in the Community" concluded that "Small, personalized, settings increase opportunities for personal satisfaction, choice, self-determination, community participation and feelings of well-being. Small settings are similarly associated with decreases in (1) the use of services, (2) feelings of loneliness and (3) service-related personnel and other costs."

This conclusion was echoed in a 2014 policy research brief by Nord, et al., "Residential Size and Individual Outcomes: An Assessment of Existing National Core Indicators Research." Nord reviewed National Core Indicator (NCI) studies published over the last decade, examining numerous outcomes for people with an intellectual disability living in different residential settings. The review found that, across all outcome areas, smaller settings, on average, produce better quality of life outcomes for people with an intellectual disability and concluded that "people living in their own homes, family homes, host family homes or in small agency residences (six or fewer residents) ranked consistently better in achieving positive outcomes than moderate size (7-15 residents) and large agency residences and institutions (more than 15 residents). Also, people living in their own homes, small agency residences, and host family homes reported more independence and more satisfaction with their lives."

In relation to the economic impact of the size limitations for day facilities in the final-form regulation, roughly 40% of day facilities funded by the Department currently serve 25 or fewer individuals, demonstrating that smaller facilities are fiscally sustainable. These facilities are located in rural, suburban and urban areas. Given the exemptions for existing facilities with application of the size limits only to new facilities, as well as a fee schedule rate structure that accounts for an individual's needs, there is no negative economic impact to the regulated community.

§ 6100.445 (§ 6100.447 in proposed rulemaking)—Locality of service location

In subsection (a), the IRRC asks to set a measurable standard or delete "in close proximity." A provider association, plus numerous form letters from commentators, a few county governments and several providers ask to define "close proximity," considering the necessary difference for urban and rural settings. An advocacy organization and a family ask to allow facilities to be located near

nursing facilities and hospitals. A university supports the alignment with the CMS regulation in 42 CFR §§ 441.300—441.310.

In subsection (b), the IRRC asks how the limit of 10% was established and to explain the reasonableness and economic impact on residential facilities. The IRRC and a few housing experts assert that the 10% restriction virtually eliminates housing opportunities for Medicaid waiver enrollees with non-physical disabilities to live in certain urban communities and that this is a profoundly unfunded mandate. The housing experts suggest that the regulation unnecessarily limits housing choices, with the extreme shortage of affordable housing further limiting choice. A university supports the proposed 10% limit for group housing. A provider association, plus numerous form letters from commentators, ask to revise the 10% cap so that common sense prevails; the association maintains that it is impossible to apply this standard for a building with fewer than ten units, it is a violation to tell a person where he cannot live and 10% is illogical since 19% of people have a disability. Another provider association, plus numerous form letters from commentators, ask to reconsider the 10% maximum as this forces people into large complexes, since not even one person could live in a four unit building. A few county governments ask to set different standards for small buildings, since the 10% maximum does not work for a small building; the county governments support the intent of the proposed regulation as integration without saturation. A provider supports subsection (b) in concept, but asserts that it is impossible to know the concentration of occupants in a private apartment building. A provider asks that 10% be increased to 20%. A provider asks how this applies to urban rowhomes.

In proposed subsections (c) and (d), a provider association, plus numerous form letters from commentators, ask to require no Department approval. A few county governments comment that the CMS prohibits funding for intermediate care facilities and ask to reinforce that the Department must approve transition plans in advance. An advocacy organization asks to add that with the approval of the Department's deaf service coordinator, the Department may allow eight individuals with similar hearing needs to live in close proximity to prevent social isolation.

Response

Although the Department solicited comments on the appropriate description of "close proximity" in the proposed rulemaking preamble, as well as through multiple public forums, no suggestion regarding a precise measurable standard was offered. The Department understands the challenge of establishing a measurable standard for a variety of urban, rural and suburban localities. The commentators at large did not object to a standard on proximity; rather, the objection is to the term "in close proximity." Subsection (a) is therefore revised to delete "or in close proximity" and governs the locality of the service location by the term "adjacent," for which there were no objections. The plain meaning of "adjacent" as defined by *West's Encyclopedia of American Law*, as "parcels of land not widely separated" applies. See *West's Encyclopedia of American Law*, Edition 2. Copyright 2008. Michigan: The Gale Group, Inc.

It is reasonable and necessary for the Department to provide HCBS to individuals with an intellectual disability and autism in integrated community settings. The Department is mandated to meet the Federal regulation governing community integration in HCBS settings to continue to be eligible for Federal financial participation. Under Federal regulations, each state must establish measurable standards for providers of HCBS. Without a regulation governing the proximity of service locations, the Department risks establishing segregated service locations that would be ineligible for Federal financial participation. See 42 CFR 441.300—441.310.

Also in subsection (a), hospitals, nursing facilities and health and human service institutions are deleted from the list of locations for which a facility may not be located nearby.

Subsection (b) is revised to increase the limit on the number of units from 10% to 25% and to apply the limit to the building, rather than the development. The 25% limit is based on the Federal

Housing and Urban Development standard regarding supportive housing for persons with disabilities at 42 U.S.C.A. § 8013(b)(3)(B)(ii), regarding supportive housing for persons with disabilities. That provision requires that the total number of multi-family housing dwelling units where rental assistance is provided for supportive housing for persons with disabilities may not exceed 25% of the total.

In response to the concern about applying a percentage to a small apartment building, the resulting percentage is rounded up. For example, in a building with ten units, 25% is 2 1/2 rounded to three; with four units, 25% is one; with three units, 25% is 3/4 rounded to one; with two units, 25% is 1/2 rounded to one.

Subsection (d) is deleted as it is duplicative of § 6100.444(b)(2) (relating to size of service location). As stated by the county governments, departmental approval must be obtained in advance for any intermediate care facility conversion to assure eligibility of Federal waiver funds. A regulatory waiver will be entertained regarding the special needs of the deaf community.

§§ 2380.121—2380.128; 2390.191—2390.198; 6100.461—6100.469; 6400.161—6400.168 and 6500.131—6500.138—Medication administration; medications

The IRRC, a provider association, plus numerous form letters from commentators and several providers, question the codification of medication administration requirements in regulations. The provider association suggests that rather than promulgate regulations, the Department's medication administration training course and manual be followed to prescribe medication practices. This alternative to regulations is suggested to permit updates to medication procedures as new health care information and technology emerge.

The IRRC asks how the regulation will be updated as new health care information, practice and technology emerge.

A provider association, several providers and the IRRC ask the Department to correct discrepancies between the proposed rulemaking and the Department's medication administration training course manual.

Several providers suggest that the medication sections of the regulation are overly prescriptive and detailed.

A few county governments support the addition of medication administration for vocational facilities.

Response

Medication requirements have been codified in departmental regulations since 1991. See §§ 6400.161—6400.169 and 6500.131—6500.138 at 21 Pa.B. 3595-3647 (August 10, 1991). The 1991 regulations, and the subsequent departmental regulations specified in §§ 2380.121—2380.129, 2600.181—2600.191, 2800.181—2800.191, 3800.181—3800.189, 6400.161—6400.169 and 6500.131—6500.138 provide critical health and safety protections for individuals in the areas of safe medication storage and handling, reporting of adverse reactions and medication errors, medication administration tracking and medication administration training for non-medically licensed staff persons. As suggested by the unanimous and overwhelming comments requesting consistency and continuity across the five chapters of intellectual disability regulations, the final-form regulation codifies existing medication requirements into Chapters 2390 and 6100 and updates the requirements across Chapters 2380, 2390, 6100, 6400 and 6500. Enforcement of medication protections is critical to ensure the health and safety of the individuals who receive services in the programs governed by Chapters 2380, 2390, 6100, 6400 and 6500.

In response to concerns that the regulations contain requirements likely to be governed or amended by other State agencies or new statutes, the Department conducted a careful review and found three requirements that warranted revision. The requirement for the content of a pharmacy label is unnecessary, as this is governed by applicable pharmacy regulation in 49 Pa. Code § 27.18(d) (relating to standards of practice); therefore, proposed §§ 2380.124, 2390.194, 6100.464, 6400.164 and 6500.134 are deleted. The regulation in 49 Pa. Code § 27.18(d) requires that a container in which a prescription drug or device is sold or dispensed include the following: the name, address, telephone number and DEA number of the pharmacy; the name of the patient; full directions for the use of its contents; the name of the prescriber; the serial number of the prescription and the date originally filled; the trade or brand name of the drug, strength, dosage form and quantity dispensed; if a generic drug is dispensed, the manufacturer's name or suitable abbreviation of the manufacturer's name; and on controlled substances, the statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

The Department also updated the provision relating to the acceptance of oral orders received by a health care practitioner in final-form §§ 2380.124(e), 2390.194(e), 6100.464(e), 6400.164(e) and 6500.134(e). While the use of oral orders has lessened with the advent of written email orders, these sections are updated to reference the standards of the Department of State.

Sections 2380.122(b)(2)(vi), 2390.192(b)(2)(vi), 6100.462(b)(2)(vi), 6400.162(b)(2)(vi) and 6500.132(b)(2)(vi)which specify the types of medications, procedures and treatments that are permitted to be administered under the Department's medication administration training course, have been modified to permit the administration of any new medications, injections, procedures and treatment as permitted by State statutes and regulations.

The final-form regulations will be amended in accordance with applicable statutes and regulations as new medical information, practice and technology emerge.

The Department conducted a thorough review of its medication administration training course manual and made several edits to coincide with the final-form regulation. Several important updates were made to the course manual. The final-form regulation and the medication administration training course manual are consistent.

The final-form regulations regarding medication administration are shortened from proposed rulemaking and are generally less prescriptive than the existing regulations at §§ 2380.121—2380.129, 2600.181—2600.191, 2800.181—2800.191, 3800.181—3800.189, 6400.161—6400.169 and 6500.131—6500.138. In response to concerns about the codified practice becoming obsolete, the Department will continuously review the practice and amend the regulation if the requirements become obsolete.

§§ 2380.121, 2390.191, 6100.461, 6400.161 and 6500.131—Self-administration

A provider asks to strike "as needed" in subsection (a). A provider association, plus numerous form letters from commentators, assert that subsection (b) is incorrect and conflicts with subsection (e)(1)—(4). The same provider association asks to require that the assistive technology in subsection (c) be documented in the individual plan. A county government supports the requirement in subsection (c) to require a provider to provide or arrange for assistive technology.

Response

The qualifier "as needed" is helpful to explain that not all individuals require medication assistance. Subsections (b) and (e) are neither incorrect nor in conflict; the confusion may lie with the previous version of the medication administration training course manual that included different standards for self-administration. This discrepancy in the course manual has been corrected to

match the final-form regulation. A staff person may provide reminders and offer the medication at prescribed times to an individual who is self-administering. Subsection (e)(3) is revised to clarify this requirement.

The need for assistance with medication administration should be assessed by the individual plan team and documented in the individual plan.

§§ 2380.122, 2390.192, 6100.462, 6400.162 and 6500.132—Medication administration

A provider association, plus numerous form letters from commentators, ask to allow the administration of oxygen, catheterizations, tube feedings and similar treatment in accordance with State statutes and regulations.

A few county governments and a provider ask to assure that there is sufficient capacity to train all required staff persons.

The IRRC and numerous commentators ask the meaning of an "00.163.163" order.

The IRRC and numerous commentators ask that licensed life sharing homes be exempted from the medication administration training requirements under § 6500.132.

The IRRC asks the Department to explain the need for, reasonableness of and fiscal impact of requiring this intensive training course for licensed life sharing homes.

A provider association asks that a nurse be required to give injections in vocational facilities.

Response

Subsection (b)(2)(vi) is revised to allow the administration of medications, injections, procedures and treatments in accordance with applicable statutes and regulations. The Department's contractor providing the medication administration train-the-trainer course has increased its training capacity and is equipped to handle the new influx of trainees.

The term "00.163.163" order was a typographical error; the error is corrected.

The Department clarified in subsection (b)(1) that any person who is so authorized by the Department of State may administer medication.

While basic training regarding safe medication handling, storage and administration is necessary to protect the individuals to whom services are provided in life sharing, in § 6100.468(b) (relating to medication administration training), both licensed and unlicensed life sharing homes will complete a shorter, modified, family-friendly medication administration training course in place of the full comprehensive course. Numerous life sharing provider agencies already require completion of the full medication administration training course by their life sharers, so completion of the new modified course may be a cost reduction. The cost of the certified train-the-trainer program is paid by the Department for a certified medication administration trainer who assists the life sharer through the modified medication administration training course.

Only injections of insulin and epinephrine are permitted by trained staff persons who are not nurses. This provision has been effectively applied in other types of licensed human service facilities for more than 10 years.

§§ 2380.123, 2390.193, 6100.463, 6400.163 and 6500.133—Storage and disposal of medications

A family asks to regulate nonprescription medications. A provider association, plus numerous form letters from commentators, ask to administer medications immediately and not permit a 2-hour

wait. An advocacy organization asks to extend the 2-hour period to allow for the transfer of medications into daily pill containers for individuals who attend day activities. A provider association, plus numerous form letters from commentators, support allowing epinephrine and epinephrine injectors to be kept unlocked and ask to allow individuals who are self-administering to place the individual's own medications in pill reminder dispensers. An adult training facility states that providing certified medication staff while the individual is out of the facility is a challenge. An adult day training facility asks that self-administering medications be kept locked and not carried or held by the individual.

Response

Nonprescription medications are regulated in subsection (a) regarding storage in the original container to protect the individual from taking an unknown or mislabeled substance.

The 2-hour time frame between removal of a medication from its original container and administration of the medication is deleted. Medication must be administered immediately upon its removal from the original container.

Sections 6100.463(b), 6400.163(b) and 6500.133(b) are revised to permit the transfer of a medication by a staff person into a daily dispenser for an individual to take to a community activity for administration the same day. Ideally, a pharmacy will prepackage daily medication into a separate container or blister pack so that staff and individuals do not have to handle the medication. The provider should ask the pharmacy to prepare multiple containers or blister packs of medication for anticipated travel or time away from the home during the day. Transfer of medications into containers is not permitted in day facilities; this practice is not necessary since the individual is at the day facility for only a portion of the day.

Subsection (h) is amended to encompass all applicable drug disposal statutes and regulations.

As described in subsection (i), this section does not apply to individuals who are self-administering; the proposed exemptions are broadened to encompass subsections (e), (g) and (h).

Staff persons responsible for administration of medication who accompany the individual while the individual is away from the service location must complete the medication administration training course. This should not be an extra burden, as the staff persons who accompany the individual into the community are likely the same trained staff persons who work in the service location.

An individual who is capable of self-administration may carry the individual's medication in a pill box or other container. If there is concern about access to the medication by other individuals who are not capable of self-administration, the individual plan team should design a solution to provide independence to the self-administering individual, while at the same time protecting others. In an adult day facility, a solution to provide independence may be to provide lockers with keys for individuals, so they may lock their belongings with free access at any time.

§§ 2380.124, 2390.194, 6100.464, 6400.164 and 6500.134—Labeling of medications in proposed rulemaking

Numerous commentators suggest deletion of the specification of the content of the medication label, as the content of the medication label is a pharmacy standard.

Response

The requirements regarding the content of the medication label are deleted. The requirement for a prescription medication to be labeled with a label issued by a pharmacy is retained and relocated to

§§ 2380.123(a), 2390.193(a), 6100.463(a), 6400.163(a) and 6500.133(a).

§§ 2380.124, 2390.194, 6100.464, 6400.164 and 6500.134 (§§ 2380.125, 2390.195, 6100.465, 6400.165 and 6500.135 in proposed rulemaking)—Prescription medications

The IRRC and several commentators ask to allow electronic prescriptions.

A provider association, plus numerous form letters from commentators, ask to allow a licensed practical nurse (LPN) to accept an oral order, as this is within the scope of practice as specified by the State Board of Nursing.

In § 6500.135(e), a provider association asks why a life sharer cannot accept oral orders.

Response

Under 55 Pa. Code § 1101.66a (relating to clarification of the terms "written" and "signature"—statement of policy), a written prescription currently includes an electronic prescription; no regulation change is necessary.

While the use of oral orders has lessened with the advent of written electronic orders, subsection (e) is revised to permit oral orders to be accepted by persons who are so authorized by the Department of State. This includes the provision for an LPN to accept oral orders.

In § 6500.134(e) (§ 6500.135(e) in proposed rulemaking), a life sharer is permitted to accept oral orders in accordance with regulations by the Department of State allowing only certain health care professionals to accept oral orders; however, given a prescriber's ability to fax or email a new prescription to a life sharer, this is not an obstacle to the provision of services.

§§ 2380.125, 2390.195, 6100.465, 6400.165 and 6500.135 (§§ 2380.126, 2390.196, 6100.466, 6400.166 and 6500.136 in proposed rulemaking)—Medication record

A few providers ask to delete the title of the prescriber. A few providers state the time frame for reporting over the weekend is not realistic. A provider asks to allow reports to a health care practitioner to include a nurse. A provider asks to clarify that a refusal to take a medication is not a medication error.

Response

The title of the prescriber in subsection (a)(2) is deleted.

Subsection (c) is revised to delete the specified reporting time frame and rely on the prescriber to direct the report. A refusal to take a medication must be reported to the prescriber only if the prescriber so directs, or if there is harm to the individual.

A refusal to take a medication is not a medication error, and therefore, a refusal to take a medication is not reportable to the Department as a medication error. Section 6100.466(a) (relating to medication errors) describes the specific conditions that constitute a medication error; the description of a medication error does not include an individual's refusal to take a medication.

§§ 2380.126, 2390.196, 6100.466, 6400.166 and 6500.136 (§§ 2380.127, 2390.197, 6100.467, 6400.167 and 6500.137 in proposed rulemaking)—Medication errors

A provider asks to change "amount" to "dose." A provider association, plus numerous form letters from commentators and several providers, ask to delete the requirement to report medication errors to the prescriber.

Response

The term "amount" is changed to "dose." Two additional types of medication errors as specified in the medication administration training course manual are added: wrong position and improper medication. The reporting of medication errors in subsections (b) and (c) is modified to delete the timeline for reporting and clarify that errors must be reported to the prescriber only under certain circumstances. Documentation of medication errors is properly recorded as an incident and in the record, not as part of the individual plan.

§§ 2380.128, 2390.198, 6100.468, 6400.168 and 6500.138 (§§ 2380.129, 2390.199, 6100.469, 6400.169 and 6500.139 in proposed rulemaking)—Medication administration training

The IRRC and a university ask to define "certified health care professional." A university asks to require additional training for topical medication. A provider association, plus numerous form letters from commentators, ask to allow the administration of epinephrine injections by untrained staff and to allow naloxone administration. Another provider association, plus numerous form letters from commentators, state that requiring epinephrine training adds significant cost. A provider supports the epinephrine addition. A few provider associations, plus numerous form letters from commentators, ask to exempt life sharers from the medication administration training course. Several providers, a county government and an advocacy organization ask that life sharers complete the full medication administration training course. A provider suggests a less stringent course for life sharers.

Response

"Certified health care practitioner" is changed to "Health care practitioner" and is clarified and described in subsection (c)(2) as a professional who is licensed, certified or registered by the Department of State in the health care field. Clarification is added to subsection (a) to allow the administration of other medications, injections, procedures and treatments as governed by statutes and regulations. In subsection (d), a shorter, modified, family-friendly medication administration training course has been developed for life sharers and other settings that are not licensed by the Department, providing protections to the individual, while not creating onerous training requirements on small settings.

The frequency of training recertification in the use of auto-injectors for the administration of epinephrine is modified from every 12 months to every 24 months to coincide with the Certified Pulmonary Resuscitation (CPR) course recertification. Training in the use of auto-injectors for the administration of epinephrine is now being taught as part of the American Heart Association and American Red Cross CPR training courses. This is a benefit for providers who will not have to plan and budget for two separate training courses.

Requiring additional training for the administration of a topical medication through the regulations is not necessary. The administration of topical medications, such as eye drops, ear drops and ointments, is properly addressed in the Department's medication administration training course by directing the certified medication trainer to obtain and follow the specific instructions of the individual's health care practitioner.

§ 6100.469 (§ 6100.470 in proposed rulemaking)—Exceptions

A provider association, plus numerous form letters from commentators, support the proposed relative exemption. A county government and an advocacy organization ask that medication administration training be required for adult family members who provide an HCBS.

Response

This section is clarified to provide that an adult relative of an individual is exempt from the medication administration training requirements, except for an adult relative of an individual who receives services in an unlicensed life sharing home or in a licensed facility. An exemption from the medication administration provisions is added for respite care and job coaches who provide fewer than 30 days of HCBS in a 12-month period.

§§ 6100.481—6100.672—General payment provisions, fee schedule and cost-based rates and allowable costs

The IRRC asks the Department's authority for setting fees by establishing a fee published as a notice in the *Pennsylvania Bulletin*. A provider association, plus numerous form letters from commentators, and several providers assert that these provisions, read in conjunction with § 6100.571 (relating to fee schedule rates), enable the Department to establish rates apart from and without compliance with an approved rate setting methodology that explains in reasonable detail the factors actually relied upon to set rates, how the factors were developed and utilized to set rates and the basis for the assumptions and presumptions relied upon to set rates. The commentators ask for more detail to understand how the new rates will operate, including specifications and metrics. Commentators ask how staff salaries and benefits will equate with the rates; without a qualified and stable work force, the regulation is for naught. An advocacy organization asks that rates be consistent across all programs, including autism.

Commentators cite 42 U.S.C.A. § 1396a(a)(13)(A), regarding State Plan requirements for public process in rate setting, and the decision in *Christ the King Manor, Inc. v. Secretary of U.S. Dept. of Health & Human Servs., et al.*, 730 F.3d 291 (3d Cir. 2013) (*Christ the King Manor*), and two other cases for the proposition that the Department must adopt a rate setting methodology that is reasonable, considers more than simple budgetary factors, results in payments to providers that are sufficient to meet individuals' needs, addresses provider viability and allows for a retained revenue factor.

The IRRC states that is it unclear how or whether there is public input in the Department's rate setting process and asks how the Department's approach is consistent with the cited court case and State and Federal law. The IRRC specifically asks how § 6100.481(b) (relating to departmental rates and classifications), which provides that the Department will establish fees by publication in the *Pennsylvania Bulletin*, is consistent with Federal law. The IRRC also asks how the Federal waiver process operates.

A legislator is concerned that the rates for both fee schedule and cost-based have stayed the same for at least five years, although the costs in the programs have increased. The same commentator is concerned that a review of the rates every five years is not sufficient to meet the annual increases faced by providers.

A few providers ask to remove all rate setting provisions from the final-form regulation, as the Department's duties are non-regulatory.

A provider association and several providers ask that the rates keep up with inflation and that an automatic cost-of-living increase be mandated in regulation.

Response

The Federal statutory authority to which the commentators cite does not govern rate setting for HCBS waiver services. By its terms, 42 U.S.C.A. § 1396a(a)(13)(A) (Section (13)(A)) applies to rate setting for hospitals, nursing facilities and intermediate care facilities for persons with intellectual disabilities. Similarly, 42 U.S.C.A. § 1396a(a)(30)(A) (Section (30)(A)) applies only to Medicaid State Plan services, not to waiver services.

For these reasons, the commentators' reliance on *Christ the King Manor* is misplaced because the Court in that case considered whether the Department and the Federal Department of Health and Human Services (HHS) complied with Section (13)(A) and Section (30)(A). In *Christ the King Manor*, nursing facilities challenged HHS's approval of the Department's Medicaid State Plan Amendment (SPA) that authorized application of a budget adjustment factor (BAF) to decrease the nursing facility payment rates by more than 9% below the rates developed in accordance with the Department's regulations. The plaintiffs claimed that the Department's public notice failed to comply with the requirements specified in Section (13)(A) and that HHS improperly approved the SPA because it did not consider whether the BAF-adjusted payment rates accounted for the quality of care, as required by Section (30)(A).

The Court determined that the Department complied with Section (13)(A) but that HHS failed to explain, on the evidence before it, how the SPA complied with Section (30)(A). Specifically, the Court concluded that it could not "discern from the record a reasoned basis for the agency's decisions" to approve the SPA. *Christ the King Manor*, 730 F.3d at 314. The case was remanded, and after reconsideration, HHS again approved the SPA. Subsequent litigation resulted in judgment in favor of HHS.

Although the cited authorities do not apply to the rate-setting methodology for waiver services or, more specifically, to the rate-setting methodology established in Chapter 6100, the Department has adopted a rate-setting methodology that considers more than simple budgetary factors and that results in payments to providers that are sufficient to meet individuals' needs. To that end, the rate-setting methodology in this chapter identifies the specific factors considered in setting the payment rates and employs a public process to allow for notice and comment.

As described in its approved HCBS waivers, the Department establishes the fee schedule rates to fund services at a level sufficient to ensure access, encourage provider participation and promote provider choice, while ensuring cost effectiveness and fiscal accountability. To identify the factors to use to develop the rates, the Department looked to the CMS guidance set forth in *Fee Schedule HCBS Rate Setting: Developing a Rate for Direct Support Workers* at https://www.medicaid.gov/medicaid/hcbs/downloads/hcbs-1a-ffs-rate-setting.pdf and *Rate Methodology in a FFS HCBS Structure* at https://www.medicaid.gov/medicaid/hcbs/downloads/rate-setting-methodology.pdf.

Using the factors enumerated in that guidance, the Department develops the fee schedule rates using a market-based approach. "Market-based approach" refers generally to the process of establishing a price for a service based upon existing market conditions, taking into consideration the rate factors that reflect the economic principle of supply and demand.

The Department's HCBS waivers describe the market-based approach process as including a review of the service definitions and allowable cost components which reflect costs that are reasonable, necessary and related to the delivery of the service as defined in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, codified at 2 CFR Part 200. For instance, direct staff wages are the largest component of the rates paid for most HCBS waiver services. To establish the rates for these services using a market-based approach, the Department examines current wage data for similar job classifications across the Commonwealth to determine what wage the market would require to attract individuals to these types of positions. Similarly, for a rate component such as health care costs, the Department examines current health care cost data across the Commonwealth to establish rates that are consistent with "market" costs.

In accordance with 42 CFR § 441.304(e) (relating to duration, extension and amendment of a waiver), the Department provides public notice by publishing in the *Pennsylvania Bulletin* a description of its rate-setting methodology, including a discussion of the specific data and data sources used and the rate-setting factors. See § 6100.571(d). Section 6100.571(a) requires that

payment rates be consistent with efficiency, economy and quality of care. In addition, under general medical assistance payment regulations, fee schedule rates, procedures and services are authorized to be added or deleted by publication of a notice in the *Pennsylvania Bulletin*. See 55 Pa. Code § 1150.61(a) (relating to guidelines for fee schedule changes).

The Department intends to provide the public with at least 30 days notice to comment on the rate-setting methodology and provider payment rates, whenever feasible. When 30-day notice is infeasible, such as when changes in Federal law require a shorter comment period, the Department will provide as much notice as possible prior to the effective date of any final provider payment rates.

In response to questions about the Department's authority to enforce the waivers through incorporation by reference in the regulation, proposed § 6100.481(a)(6), which referenced the Federal waivers, is deleted.

In response to IRRC's question on how the Federal waiver process operates, please refer to the Background section of this preamble.

Section 6100.481(c) and (d) is revised to clarify that the fee is per unit of an HCBS.

Section 6100.571(a) is significantly revised to address the concerns of the commentators. See discussion relating to comments and the specific changes to the final-form regulation in § 6100.571(a)—(e).

Section 6100.571(c) mandates that the market-based data be updated at least every 3 years.

A cost-of-living increase is not included in the final-form regulation as the General Assembly appropriates HCBS funds through the Commonwealth's annual budgeting process, and such an increase is not required by Federal or State law.

§ 6100.482—Payment

A provider maintains that Chapters 1101 and 1150 apply to medical services and not to an HCBS. A provider association, plus numerous form letters from commentators, and a provider ask to permit flexibility, backdating and emergency exceptions in the frequency and duration statement. A provider association asks to change "and" to "or" in subsection (h). A provider asks to extend services beyond the individual plan.

Response

Chapter 1101 contains the general requirements that apply to providers enrolled in the medical assistance program. To be an HCBS provider, medical assistance program enrollment is required; therefore, Chapter 1101 applies to HCBS. See § 6100.81(b)(1) (relating to HCBS provider requirements), which requires an HCBS provider to comply with Chapter 1101.

The Department agrees with the commentator that Chapter 1150 does not apply to HCBS, because Chapter 1150 applies to medical assistance provider payment provisions and not to HCBS. Chapter 6100 governs the payment provisions for HCBS.

Consistent with previously discussed comments and changes, in response to questions about the Department's authority to enforce the waivers, subsection (a) is revised to delete reference to the Federal waivers.

Subsection (c) is revised so that the amount, duration and frequency is as approved and documented in the individual plan; services must be specified in an approved individual plan in order to be reimbursable by the CMS. Sections 6100.223(6) and 6100.226 (relating to

documentation of claims) provide reasonableness and clarity regarding the application of claims documentation to the extent permitted by the CMS.

In subsection (h), the term "and" is changed to "or" as suggested.

§ 6100.483—Title of a residential building in proposed rulemaking

A provider association, plus numerous form letters from commentators, and a few providers ask to delete this section as unnecessary as the title to real estate acquired by a provider clearly remains with the provider who owns it.

Response

This section is deleted as unnecessary.

§ 6100.484 (§ 6100.485 in proposed rulemaking)—Audits

A provider association, plus numerous form letters from commentators, an advocacy organization and several providers ask to reduce this list of audit standards as the list is overly inclusive, suggesting subsection (a)(1) and (a)(2) are sufficient.

Response

This section is revised to delete proposed (a)(4)-(j) as unnecessary since these standards and audit sources are governed by other State and Federal agencies and governing authorities. Subsection (a)(3) regarding the United States Office of Management and Budget Circulars is retained as a primary authorized source of audit standards.

§ 6100.485 (§ 6100.487 in proposed rulemaking)—Loss or damage to property

A provider asks to limit the requirements of this section to only damage or loss that occurs during the provision of an HCBS. A provider association, plus numerous form letters from commentators, ask that the provider be required to replace property only if staff is negligent or if the damage or loss is otherwise the fault of the provider. The same provider asks to allow for repair of the damaged property, if possible. A provider asks to delete damage due to normal wear and tear.

Response

The proposed rulemaking and the final-form regulation limit the damage or loss to that which occurs during the provision of an HCBS. The section is revised to clarify that this provision applies only if the damage or loss is due to the provider's action or inaction; this does not include damage or loss caused by the individual. Repair of an item is allowed and is added to this section.

§ 6100.571(a)—Fee schedule rates

Numerous advocates, universities, county governments, providers, provider associations and the IRRC submitted comments on § 6100.571. A provider association, plus numerous form letters from commentators, ask the Department to obligate itself to use the data in proposed subsection (b) to develop the rates. The same provider association asks the Department to use the United States Department of Labor standards and labor statistics to develop the rates. An advocacy organization, a family and several providers ask to use a nationally recognized market-based index, such as the Consumer Price Index or Medicare Home Health Market Basket Index. An advocacy organization asks to specify the HCBS covered under each payment option, such as fee schedule and cost-based. A few providers ask the Department to apply the data provided by the ODP Bureau of Autism Services and Autism Services, Education, Resources and Training (ASERT) when developing the autism rates.

In response to the advance notice of final rulemaking, a commentator, plus numerous form letters from commentators, ask that the rates reflect the costs to provide quality care based on the documented needs of the individuals as set forth in the individual plans. Another commentator, plus numerous form letters from commentators, ask that a nationally recognized market index be used to adjust the rates annually. Another commentator, plus numerous form letters from commentators, ask that an annual inflation factor be required. The same commentator asks to require the Department to include in its annual budget to the Governor the funding necessary to support the Medicare Home Health Market Basket Index to recalculate the fee schedule rates and update the rates to the following fiscal year.

Response

Subsection (a) is revised to clarify that the Department will establish fee schedule rates using a market-based approach so that payments are consistent with efficiency, economy and quality of care and sufficient to enlist enough providers so that services are available to at least the extent that such services are available to the general population in the geographic area.

The fee schedule rates cannot be based upon the needs specified in individual plans. The CMS requires that the fee schedule rate methodology result in a consistent rate paid to all providers of the same service. There are more than 53,000 individuals receiving HCBS and their needs are continuously changing. As specified in § 6100.571(b)(1), rates are based on levels of need to account for individuals with more intense staffing, behavioral, medical and other needs.

The specific market-based index is not specified in the regulation; rather, the Department will establish fee schedule rates using a market-based approach based on the following factors: the service needs of the individuals; staff wages; staff-related expenses; productivity; occupancy; direct and indirect program and administrative expenses; geographic costs; the Federally-approved HCBS definitions in the waiver; the cost of implementing Federal and State statutes and regulations and local ordinances; and other factors that impact costs. The Department will update this data at least every 3 years as specified in subsection (c).

In addition, an annual inflation factor is not included in the final-form regulation. The General Assembly appropriates HCBS funds through the Commonwealth's annual budgeting process. The frequency of the data update addresses concerns related to the potential of increased costs over time. Previous drafts of the proposed regulation included a periodic data update and a 4-year data update. Further, the Department may choose to update the data more frequently than every 3 years.

Unnecessary restrictions specifying the types of HCBS covered under each payment option, such as fee schedule and cost-based, are not codified in the regulation to permit a change to payment methodologies as new and innovative payment methodologies and services emerge.

The same general methodology described in § 6100.571 is used to set rates for autism services.

§ 6100.571(b) (§ 6100.571(c) in proposed rulemaking)—Fee schedule rates

A university supports the enumerated factors used to establish rates. The IRRC asks the Department to clarify the term "consider" to set binding norms of general applicability and future effect, to set clear standards of compliance and to provide predictability for the regulated community. An advocacy organization and a provider association, plus numerous form letters from commentators, ask that the Department mandate itself to take the factors into account, rather than to simply review and consider the factors.

In subsection (b)(2) ((c)(2) in proposed rulemaking), a university asks to use staff wages commensurate with work, skills and competency requirements. In subsection (b)(2), the university

asks to limit executive salaries based on the funding level and services provided. In subsection (b)(3) ((c)(3) in proposed rulemaking), the university asks to add staff training costs.

A commentator is concerned about an individual's unexpected and unpredictable decline that is limited to a supports intensity scale (SIS) score that is reviewed every 5 years; even with a request for a new assessment, it will take time to obtain an updated SIS score, while the cost of providing additional services is placed on the provider with no guarantee of reimbursement. Several providers ask what happens if an individual's service needs change more often than every 3 years.

The IRRC and several commentators ask to delete subsection (b)(7) ((c)(7) in proposed rulemaking) since services may be provided outside the geographic region where the provider's office is located. The IRRC asks to explain the reasonableness of this subsection.

A provider association proposes an extensive rewrite of this subsection to require an update of the data every 3 years to reflect current costs, require the Department to publish a rate setting methodology describing the process and the rates in detail and apply the Medicare Home Health Market Basket Index.

In response to the advance notice of final rulemaking, one commentator asks that staff expenses factor in actual expenses based on the annual cost reports submitted by providers, including administrative costs higher than 15%, staff training and flexibility in the rates based on staff ratios. A commentator asks to include market costs for housing, utilities, food and geographic data related to a living wage. A commentator asks for detail in the kinds of data to be used and that data relate to the intellectual disability service system. A commentator supports the inclusion of staff benefits, training, recruitment and service needs. A commentator, plus numerous form letters from commentators, ask that service needs reflect the specific needs in each individual plan. A few commentators believe that the proposed factors reflect the needs of a group setting operated by a large provider, and that the factors are not relevant for a residence for one individual or for a small provider. A provider association, plus numerous form letters from commentators, ask to qualify staff benefits as health care and retirement benefits and refer to benefits using the term "such as" rather than "including." A commentator states that the current staff training rates are well below actual costs; the commentator asks that the rates reflect the costs to acquire the required skills and the costs to administer medication and medical procedures. In response to the advance notice of final rulemaking, a commentator, plus numerous form letters from commentators, ask to clarify "occupancy" and "direct and indirect" expenses.

In response to the advance notice of final rulemaking, one commentator asks how subsection (b)(7) ((c)(7) in proposed rulemaking) permits a single Statewide rate. A commentator states that the legislature defines the classes of cities based on population. Several commentators oppose one Statewide rate, requesting that the southeast area of the State, and in particular Philadelphia, receive higher rates than the rest of the State based on local ordinances requiring higher minimum wages, insurance rates and wage taxes.

In response to the advance notice of final rulemaking, a commentator asks to add that cost components reflect reasonable and necessary costs.

In response to the advance notice of final rulemaking, a commentator asks that ramp up costs be factored in by adding another factor or in some other way.

Response

The Department is sensitive to the concerns that rate setting may produce rates below the providers' costs and that established rates may not increase at the same pace to reflect changes in the costs to provide services. Subsection (b) is revised to require the Department to "examine and use" the specified factors in establishing the fee schedule rates.

The Department follows the CMS guidance for establishing fee schedules found at *Rate Methodology in a FFS HCBS Structure* at https://www.medicaid.gov/medicaid/hcbs/downloads/rate-setting-methodology.pdf. In accordance with this guidance, the calculation of the staff wages factor in education, experience, licensure and certification and data from the Bureau of Labor Statistics for Pennsylvania. The suggested clarification to include education, experience, licensure requirements and certification requirements is added to subsection (b)(2) ((c)(2) in proposed rulemaking).

Data sources that include data for staff positions comparable to the staff positions in the intellectual disability and autism system are used since there are no national intellectual disability or autism staffing data sources. In accordance with the CMS guidance, found at *Rate Methodology in a FFS HCBS Structure*, the fee schedule is developed according to service levels; the data sources use U.S. Bureau of Labor Statistics data by job classification. In addition, the commentators' assertions about staffing costs are not accurate; residential rates are based on the acuity of the individual and thus reflect staffing costs in both individual and group settings and for large and small providers. The cost to learn and maintain required skills, including medication administration and the provision of health care, is addressed in paragraphs (1), (2), (3) and (8). Therefore, these costs are factored into the rates.

In subsection (b)(3) ((c)(3) in proposed rulemaking), the requested change to add staff benefits, training, recruitment and supervision costs is made. Staff training costs are examined and used as an important factor to determine the fee schedule rates for program support costs and training time, as provided by the CMS guidance found at *Rate Methodology in a FFS HCBS Structure*. Staff training costs are appropriately and adequately addressed in paragraphs (1), (2), (3) and (8). The term "benefits" is not qualified since the commentator's requested language suggests that the types of benefits to be considered may be limited to health care and retirement; benefits may also include family leave, sick leave and vacation leave. The term "including" is appropriate since it means that the Department must consider benefits; the term "such as" suggested by the commentator means that benefits may or may not be considered. Therefore, the Department did not make the change.

In subsection (b)(6) ((c)(6) in proposed rulemaking), administrative-related costs, which encompass executive salaries, are calculated in accordance with the CMS guidance for establishing fee schedules found at *Rate Methodology in a FFS HCBS Structure*. As such, in subsection (b)(6) ((c)(6) in proposed rulemaking), there is no specific restriction regarding executive salaries. As suggested by a provider association, program expenses are clarified to include both direct and indirect expenses.

In subsection (b)(4) and (b)(5) ((c)(4) and (c)(5) in proposed rulemaking), "productivity" and "occupancy" are defined. Productivity and occupancy vary by the service type. In the publication of the fee schedule notice, detail is provided for each factor with an opportunity for public comment. Separate from the rate setting process, but related to occupancy, if residential occupancy is decreased due to a vacancy, the Department has a procedure to adjust the rates accordingly. See § 6100.55.

Subsection (b)(7) ((c)(7) in proposed rulemaking) regarding geographic region is revised to require the factor to apply to the geographic location of where the HCBS is provided, rather than the office location of the provider agency. The regulatory language requires that geographic costs based on location be considered, but it does not require the establishment of varied geographic rates. For fiscal year 2017-2018, the data supports one Statewide rate.

In subsection (b)(8) ((c)(8) in proposed rulemaking), "reasonable and necessary" costs are included as suggested by the commentators.

Subsection (b)(9) ((c)(9) in proposed rulemaking) requires consideration of local ordinances, such as minimum wage and wage tax requirements, that contribute to costs for any of the preceding

factors. Minimum wage and the wage tax requirements, such as those referenced for Philadelphia, were specifically considered when developing the language for subsection (b)(9).

Ramp up costs, also known as start-up costs, are addressed on a case-by-case basis. The need for start-up costs is infrequent and varies based on a limited number of users in the system; therefore, it is not appropriate to address start-up costs as part of the fee schedule.

In response to the concern about SIS assessments and the ability to quickly adapt to changing individual needs and adjust the fee schedule rate accordingly, the service needs of the individual are not dependent on or related to the 3-year data update in subsection (c); rather, if an individual's acuity level changes, the accompanying fee schedule rate may be assigned. SIS assessments are routinely conducted every 5 years for individuals receiving HCBS. While a SIS assessment is required to evaluate and validate the change in needs, an assessment will occur promptly if the request for reassessment indicates a significant change in the individual's health and safety needs. The Department considers a significant change any major change in an individual's life that has a lasting impact on the individual's service needs, is anticipated to last more than 6 months, and makes the individual's SIS assessment inaccurate and no longer current. Types of changes that may be considered include health status; behavioral issues; skills and ability; or the availability of technology. These are changes that the individual experiences that may cause the individual's service needs to increase or decrease. For example, an individual could have a change in the individual's medical condition that requires more intensive supports; or, an individual could receive new assistive technology and, therefore, have less intense service needs than before acquiring the new technology.

§ 6100.571(c) (§ 6100.571(b) in proposed rulemaking)—Fee schedule rates

A provider association, plus numerous form letters from commentators, ask to use the term "rebase" rather than "refresh." A county government, a provider association and a provider support the 3-year data refresh. An advocacy organization, a few provider associations, plus numerous form letters from commentators and several providers, ask to refresh the data every year; they state that anything less frequent than 1 year is unfair and forces a provider to compromise the quality of care or operate at a loss. A few provider associations, plus numerous form letters from commentators, and several providers ask that an annual cost-of-living increase be mandated in the regulation.

In response to the advance notice of final rulemaking, several commentators ask to update the data used to develop the rates annually, rather than every 3 years.

Response

The section is simplified to use the term "update" rather than "refresh" or "rebase." The term "update" is the appropriate term, as it requires the Department to revise, examine and use the data in the rate setting process. "Rebase" is a term used in cost-based methodology and is not appropriate in a fee schedule system.

The frequency of the data update remains as proposed as at least every 3 years. Previous drafts of the proposed regulation included a periodic update and a 4-year data update. The cost to the Commonwealth to conduct a data update is about $500,000. More frequent data updates will not produce sufficient variation in the data to warrant the added expense to the system that is better spent on delivering HCBS to individuals. The Department may update the data more frequently than every 3 years, as the language requires the update to be done "at least every 3 years."

A cost-of-living increase is not included in the final-form regulation as the General Assembly appropriates HCBS funds through the Commonwealth's annual budgeting process.

§ 6100.571(d)—Fee schedule rates

See comments discussed in *§§ 6100.481—6100.647—General payment provisions, fee schedule and cost-based rates and allowable costs*.

A provider asks to allow providers 30 days to comment on the proposed rates.

In response to the advance notice of final rulemaking, a commentator asks to revise the term "summary," stating that a "summary" is not sufficient. The same commentator asks the Department to publish a second notice to address the public comments.

The IRRC, another commentator, plus numerous form letters from commentators, ask that if a formula is not adopted in the regulation, the Department must be clear and precise in explaining all the factors and data used to calculate the rates. The same commentator suggests that a new regulatory section be added to regulate the SIS score.

Response

Significant changes are made to this subsection. The term "summary" has been changed to "description" to better prescribe the level of detail to be provided in the Department's notice. The Department will publish a description of its rate setting methodology as a notice in the *Pennsylvania Bulletin* for public review and comment. The description will include a discussion of the use of the factors in subsection (b) to establish the fee schedule rates, a discussion of the data and data sources used and the fee schedule rates.

While the public comment period is not specified in the regulation, a public comment period of 30 days will be provided to the extent practicable.

In final-form subsection (e), the Department will make available to the public a summary of the public comments received in response to the notice in final-form subsection (d) and the Department's response to the public comments.

A new section relating to the SIS scale may not be added to the final-form regulation as this new provision would enlarge the purpose of the proposed rulemaking, which is prohibited by the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1202), known as the Commonwealth Documents Law. The Department may make "such modifications to the proposed text as published pursuant to section 201 as do not enlarge its original purpose." 45 P.S. § 1202.

§ 6100.641—Cost-based rate

An advocacy organization and a provider ask why this section refers to residential services when the Department plans to move to a fee schedule system.

Response

Subsection (b), which referred to residential services, is deleted.

§ 6100.642—Assignment of rate

An advocacy organization asserts that basing rates on cost reports means that the rates do not reflect actual costs, current costs or the wishes of the individuals. Another advocacy organization and a family assert that using area adjusted rates in subsections (b) and (c) will be a disincentive for providers from serving individuals with higher needs. A provider asks to determine rates based on the region and not using a Statewide model. An advocacy organization asserts that assigning the lowest rate in subsection (d) penalizes individuals and leads to deterioration in the quality of services.

Response

The Department agrees with the comments that basing rates on cost reports is not the most effective payment methodology for intellectual disability and autism services, that the cost-based methodology may be a disincentive for providers to serve individuals with higher needs and that assigning the lowest cost-based rate may affect quality of services; therefore, the Department transitioned from a cost-based system to a fee schedule system for residential services effective January 1, 2018. The fee schedule rates consider the needs of the individual as one of the factors in establishing rates. See § 6100.571 (relating to fee schedule rates). Sections 6100.641—6100.672 continue to be necessary for transportation services and for any future HCBS for which a cost-based system is appropriate.

The comment relating to determining rates based on regions is addressed in § 6100.571(b)(7) that requires the Department to examine and use data regarding geographic costs, based on the location where the HCBS is provided, as one of the factors in establishing the fee schedule rates. While a single Statewide rate is not prohibited by subsection (b)(7), geographic costs must be examined and used in establishing the rates.

§ 6100.643—Submission of cost report

The definition of "cost report" is relocated to § 6100.3.

§ 6100.645—Rate setting

An advocacy organization states that the use of the outlier analysis has led to substantial reductions in rates for individuals with the most intensive service needs and that services have been denied, violating unspecified provisions of Title XIX of the Social Security Act.

Response

The requirement in subsection (e) ((f) in proposed rulemaking) regarding the outlier analysis does not result in a denial of services.

Consistent with previous comments and changes, in response to questions about the Department's authority to enforce the waivers through incorporation by reference in the regulation, proposed subsection (e) is deleted as it references the Federal waivers.

Subsection (e) ((f) in proposed rulemaking) is revised to clarify that the Department's review of the cost report is the Statewide process used to review the cost reports.

§ 6100.646—Cost-based rates for residential service

A provider association, plus numerous form letters from commentators, ask to clarify what happens when a unit cost is identified as an outlier and how a vacancy factor will be calculated. A provider association, plus numerous form letters from commentators and a few providers, ask to divide a provider's allowable costs by the provider's billed days. A provider association and a provider ask that the vacancy factor assessment and the percentage be based on current and historical data.

Response

Effective January 1, 2018, with the transition of residential rates to the fee schedule, this section no longer applies to residential service rates. For fee schedule rates, occupancy is a factor used in calculating the rates. See § 6100.571.

In response to the comments about outliers and vacancy factors, the Department previously identified a unit cost as an outlier when that unit cost was at least one standard deviation outside the average unit cost as compared to other cost reports submitted. A vacancy factor is defined in §

6100.3 as an adjustment to the full capacity rate to account for days when residential service providers cannot bill due to an individual not receiving services. The vacancy factor for residential habilitation was previously calculated based on historical data for all residential service locations, as the current data will not have undergone an independent audit. The unit cost was previously calculated as reported on the cost report, rather than as costs divided by billed days.

§ 6100.647—Allowable costs

A provider association, plus numerous form letters from commentators and a provider, ask to delete this section as vague and unnecessary. A provider asks that payment be made for outcomes delivered, rather than by cost reports. A few providers state that this should not apply once the conversion is made to the fee schedule.

Response

This section is retained as necessary to govern transportation services and allow for use of a cost-based system in the future, if deemed appropriate. The section provides sufficient detail by specifying the requirements for the best price by a prudent buyer, relating the cost to the administration of the HCBS, the allocation and distribution of costs, reference to and criteria for allowable costs and transactions between related parties.

The comment suggesting payment for outcomes delivered, rather than by cost reports, is supported. The Department has converted residential services from a cost-based payment methodology to a fee schedule payment methodology, effective January 1, 2018.

As discussed previously, in response to questions about the Department's authority to enforce the waivers, the reference to the Federal waivers in subsection (d) is deleted.

§ 6100.648—Donations in proposed rulemaking

The IRRC, a few provider associations, plus numerous form letters from commentators and several providers, ask why limitations on donations are imposed in a single payer system in which the Department does not participate in fundraising efforts.

Response

The proposed section regarding donations is deleted.

§ 6100.648 (§ 6100.486 in proposed rulemaking)—Bidding

The IRRC and other commentators request this provision not apply to a fee schedule model. The IRRC asks why a provider must obtain supplies and equipment using a competitive bidding process. A few providers ask to set the threshold at $25,000; a few other providers ask to limit the bidding to new purchases over $10,000.

Response

This section does not apply to a fee schedule payment system; as such, the section is relocated from the general payment section to apply only to the cost-based provisions in § 6100.648 (relating to bidding). A bidding process is necessary for a cost-based program to assure that fair and reasonable prices are paid. The $10,000 limit is fair and reasonable. The standards for bidding assure fiscal accountability in the careful and prudent use of State and Federal taxpayer dollars, similar to obtaining several private contractor bids for a home renovation project. The bidding provision applies only to cost-based services.

§ 6100.650—Consultants

The IRRC and commentators ask why the written agreement with a consultant in subsection (b)(3) must include the method of payment and why benefits are not allowable in proposed subsection (c). The IRRC asks to explain the reasonableness and fiscal impact of these provisions.

Response

In subsection (b), executing written consultant agreements that include the method of payment is a common and acceptable business practice. There is no economic or fiscal impact for this provision as most providers already execute such contracts. Written agreements are necessary to provide fiscal accountability for the public funds.

Subsection (c) governing benefits is deleted. Benefits for a consultant are allowable if the costs are built into the contractor's fee; this occurs through the contractor's agreement with the provider. For example, a contractor's fee may include the cost of vacation time, retirement, health benefits, travel expenses or other benefits built into the overall consultant fee.

§ 6100.651—Governing board

A university asks to require training on the CMS regulation in 42 CFR §§ 441.300—441.310 and Statewide transition for the governing board members.

Response

The specific types of governing board training suggested are supported by the Department, but are not appropriate for regulation.

Clarification is added to subsection (c)(1) regarding the lack of restriction to supplement the expenses of the board.

§ 6100.652—Compensation

The IRRC asks the Department to explain why a bonus or severance payment that is part of a severance package is not allowable and the fiscal impact of this restriction. A provider association, plus numerous form letters from commentators, ask to allow bonuses and severance not to exceed a 3-month salary. Another provider association, plus numerous form letters from commentators, ask to combine subsections (b) and (c). A third provider association asks to delete subsection (b), stating that Circular A122 allows severance pay in certain circumstances. A provider states that this is the cost of doing business and should be allowed.

Response

Subsection (b) is clarified to state that a bonus that is not part of a compensation package is not allowed. If the bonus or severance is part of a compensation plan, agreement or package, it is permitted with no limitations. The intent of this provision is to limit the use of taxpayer dollars for unplanned bonuses and severances. This limits the amount of unplanned high-level bonuses, often known as golden parachutes, to reduce the cost impact on the Commonwealth, allowing HCBS funds to be dedicated to providing HCBS to the individuals.

The Department did not combine subsections (b) and (c) since shorter and distinct sections are easier to read.

§ 6100.657—Rental of administrative equipment and furnishing

Consistent with current practice, this section is clarified to apply to administrative equipment and furnishings.

§ 6100.659—Rental of administrative space

Regarding subsection (a), a provider association, plus numerous form letters from commentators, suggest that there should be no difference in an allowable cost for administrative space due to the relationship with the lessor; the rental charge should be the same whether the lessor is a related party or not.

In subsection (a)(1), a provider suggests that it is not practical to ask a lessor to put this language in its lease; it is the provider's duty to get the best rates on the leased space. A few other providers agree and ask to delete this requirement.

A few providers ask to delete the word "minimum" in subsection (c).

Response

These changes are made. Subsection (a)(1) is changed to reflect that there is no difference in an allowable cost for administrative space due to the relationship with the lessor. Further, subsection (a)(1) is changed to eliminate the requirement regarding the lease with a related or an unrelated party. Subsection (c) is changed to delete the requirement that expenses relate to the minimum amount of space necessary.

§ 6100.660—Occupancy expenses for administrative buildings

A few providers ask to strike the requirement to document utility costs at fair market value as the provider has little control over these costs. A provider association asks to add maintenance costs as an allowable expense.

Response

These changes are made.

§ 6100.661—Administrative fixed assets

The IRRC and several commentators state that subsection (h) does not consider that there may be fixed assets that are ineligible, in support of homes and reimbursed as ineligible on the fee schedule, and other assets that are eligible in support of administration and reflected on the cost report. The IRRC asks to explain the reasonableness and the economic impact of this provision.

Regarding subsection (i)(2), a provider association, plus numerous form letters from commentators, ask to clarify that (i)(2) applies as related to the eligible waiver program. The same provider association believes that in subsection (i)(3), an annual inventory is burdensome and should be completed at the discretion of the provider.

Response

Subsection (h) is revised to require the provider to apply the revenue amount received through the disposal of a fixed asset to any eligible or ineligible expenditure. This provision allows providers to apply revenue from disposal of fixed assets to any expenditure described in § 6100.647 (relating to allowable costs) or apply the revenue to expenditures that fall outside the definition of allowable costs, but occur in the course of providing HCBS. With this change, there is no economic impact for this provision.

Subsection (i)(2) is revised to clarify that this applies to eligible HCBS expenditures.

Subsection (i)(3) is revised to delete the timing of the annual inventory; however, an annual inventory is necessary for public fund accountability and audit purposes.

§ 6100.662—Motor vehicles

Several providers state that maintaining a daily log is unnecessary and onerous. A few providers ask to require documentation of fair market value. A provider association, plus numerous form letters from commentators, ask to specify how a provider must analyze and compare vehicle rental versus purchase.

Response

No changes are made to this section. A daily log is necessary for medical assistance billing purposes. The methodology used to compare rental and purchase costs is at the discretion of the provider. The provider will compare rental and purchase costs and select the most practicable and economical alternative.

§ 6100.663—Administrative buildings

In subsection (b), a provider asks that fixed assets be defined to exclude real estate and to delete the concept of funded equity.

Regarding subsection (c), the IRRC and several commentators ask to explain the basis upon which an approval will be granted and how a provider may appeal a disapproval. A provider association, plus numerous form letters from commentators, assert that the provider should not have to obtain permission to make improvements.

In subsection (f), several commentators ask to define "funded equity" so that it does not apply to equity built or acquired through donation or fundraising. The IRRC states that other commentators ask for subsection (f) to be deleted. The IRRC asks the Department to clarify its intent and to explain the reasonableness of this provision.

A provider association, plus numerous form letters from commentators, ask to delete subsection (g) as unnecessary since the title remains with the provider that owns it.

Response

The definition of "fixed asset" is found at § 6100.3. The definition excludes real estate. The concept of "funded equity" is deleted from subsection (f).

Subsection (c) is revised to include renovations for more than 25% of the current real estate value, which will significantly increase the threshold amount requiring approval.

For any future HCBS that are reimbursed on a cost-basis, the Department's approval of the renovation is based upon the need for the administrative building and the reasonableness of the costs.

A provider may appeal a disapproval in accordance with Chapter 41 (relating to medical assistance provider appeal procedures).

Subsections (f) and (g) are deleted since the provisions are unnecessary.

§ 6100.664—Residential vacancy

A provider states that the regulation should not have an open-ended reference to a vacancy rate. A provider asks to delete the reference to a vacancy rate. Yet another provider asks to delete the vacancy rate in favor of a rate calculated by dividing actual allowable costs by the billed units of service. A few providers ask not to be penalized when an individual is on medical, hospital or

therapeutic leave. A few county governments support the clarification in subsection (e) regarding transfers of individuals due to absence.

Response

It is unclear what the commentator intended by using the term "vacancy rate." There is no specific payment rate or payment for vacancy as such a payment would not be eligible for Federal financial participation; rather, the rates reflect assumptions such as a "vacancy factor" related to non-billable time, due to vacancies when an individual is on medical, hospital or therapeutic leave. If the term is intended to capture the percentage of time the individual is absent from receiving a service, and thus non-billable time for the provider, then the term "vacancy factor" is the appropriate term. The term "residential habilitation vacancy" is changed to "residential vacancy" to align with language in the Federal waivers and to be consistent with the term as used in this chapter.

The comment regarding vacancy rate during medical, hospital or therapeutic leave is appropriately addressed in the change to § 6100.55. Provisions related to transfer of individuals are addressed in §§ 6100.302—6100.303 (relating to cooperation during individual transition; and involuntary transfer or change of provider).

Subsections (c), (d) and (e) are deleted as unnecessary in this section, since the proposed concepts are appropriately and adequately addressed in § 6100.55 and § 6100.303.

§ 6100.665—Indirect costs

A provider association and a few providers ask to omit the reference to the Federal Circulars and the cross-reference to Generally Accepted Accounting Principles (GAAP) in § 6100.647 (relating to allowable costs), as redundant.

Response

Reference to the Office of Management and Budget Circulars and the related guidance for purposes of clarifying indirect costs is not redundant and remains unchanged. Subsection (e) is deleted as unnecessary.

§ 6100.666—Moving expenses

A provider association, plus numerous form letters from commentators, ask to remove the requirement for prior approval.

Response

This change is made.

§ 6100.668—Insurance

A provider asks to require malpractice and board insurance. A provider asks to remove paragraphs (1)—(7) and require only minimum insurances.

Response

No change is made. The list of minimum insurances is reasonable and necessary to protect the public. The Department supports the provider's choice to maintain malpractice and board insurance, but this is not a mandated requirement.

§ 6100.669—Other allowable costs

An advocacy organization and a university ask to add the cost of auxiliary aids and services, including qualified interpreters.

A provider believes it is reasonable to divide the cost of legal fees between the provider and the Department if a settlement is reached. A provider association, plus numerous form letters from commentators and several providers, ask that when a provider in good faith challenges a departmental action and the parties resolve the dispute to avoid the cost and uncertainty of the litigation, the legal fees incurred by the provider must be compensated by the Department.

Response

The costs for auxiliary aids and interpreters is an allowable cost if the costs are not otherwise covered as an HCBS.

Based on long-standing Department policy, the cost to file suit against the Department is not an allowable cost if a settlement results; such cost may not be borne by taxpayers. As stated by the commentators, if a settlement is reached, much of the litigation cost is avoided.

§ 6100.670—Start-up cost

A county government supports this section, including the expansion of conditions under which start-up costs may be requested. An advocacy organization asks that the Department affirm that adequate start-up funds will be available and that funds will be available to acquire assets, including accessibility modifications. A provider asks to advance up to 25% of the first annual budget for start-up. A provider association, plus numerous form letters from commentators and a few providers, support the use of start-up funds for a business in a new geographic area, but ask that the amount for start-up must be reasonable.

Response

The expanded list of activities eligible for start-up costs remains. The authorization specifications in subsections (b) and (c) are deleted since these provisions do not require regulatory oversight. The Department cannot commit to the level of start-up funding available, as the Department's funding level is part of the Department's general appropriation subject to budget enactment.

§ 6100.672(a)—Cap on start-up cost

A provider association, plus numerous form letters from commentators, support the removal of the $5,000 cap and ask to base the limit on the needs of each individual. Another provider association and a few providers ask to set a cap at $40,000, but remind the Department that raising the cap is only useful if more funds are allocated to the Department's start-up fund. A provider states that costs can reach $100,000 for accessibility renovations such as ramps, showers and fully accessible homes.

Response

A specific cap amount was not proposed by the Department. A change is made to clarify that the Department will establish a start-up cap annually. The Department cannot commit to the level of start-up funding available, as the Department's funding level is part of the Department's general appropriation subject to budget enactment.

§ 6100.681—Room and board applicability

The IRRC and a provider association, plus numerous form letters from commentators, assert that this section should apply only to licensed facilities and not to unlicensed or apartment settings. The IRRC asks to explain the reasonableness of this provision. A provider association, plus numerous

form letters from commentators, ask to provide guidelines regarding what is included in room and board.

Response

The section is clarified to apply to provider-owned or provider-leased residential service locations and to life sharing homes that are not owned or leased by the individual. This section does not apply to most family settings, since the provider does not own or lease the property. Organized health care delivery systems and support coordination organizations are exempt from this section. See §§ 6100.803(b)(6)) (relating to organized health care delivery system) and 6100.802(d)(5)) (relating to support coordination, targeted support management and base-funding support coordination). These sections are intended to protect an individual's financial independence and security in situations where the individual has a financial relationship with the provider (whether licensed or unlicensed) because the provider owns or leases the residential service location.

In response to the comments, § 6100.684(d) (relating to actual provider room and board cost) clarifies what is included in room and board costs.

§ 6100.682—Assistance to the individual

A provider states that the responsible party is the family or support coordinator. A provider association and a provider state that the phrase "if desired by the individual" is not consistent with landlord-tenant agreements that bind a lessee through an agreement.

Response

This section applies to individuals who reside in provider-owned or leased residential service locations and in life sharing homes that are not owned or leased by the individual. The support coordinator is responsible for assisting the individual to apply for supplemental security income (SSI) benefits. In addition, providing SSI benefit assistance to individuals has been done by providers for decades in accordance with Chapter 6200 (relating to room and board charges).

The phrase "if desired by the individual" in subsection (b) is deleted; if an appeal is not filed and no SSI is received, the provider may not get paid, since room and board is collected based on available income. The application for benefits, and the subsequent appeal if SSI benefits are denied, is necessary. Subsection (d) is relocated from proposed § 6100.687 (relating to documentation).

Proposed § 6100.444 (relating to lease or ownership) is deleted; further, all references to leases are deleted in response to public comment.

§ 6100.684—Actual provider room and board cost

A provider association, plus numerous form letters from commentators, ask to require a new room and board contract once each year, rather than each time a contract is signed. The same provider association asks if the room and board costs are calculated per site or in the aggregate; the association recommends that costs be done in the aggregate. Another provider association asks to clarify the documented value of room and board. A provider states that this proposed section regarding actual room and board costs will make U.S. Department of Housing and Urban Development (HUD) vouchers more difficult for supported living.

Response

While the provider must recalculate the room and board costs when a new contract is signed, changes outside of the annual renewal are unlikely. A change most often occurs due to a move to a

new location and then room and board must be recalculated. If the new contract is due to a change in representative payee assignment, the costs are re-verified and the agreement is re-signed.

Costs are based on the actual room and board costs for a specific location, not in the aggregate. This process has been in effect under Chapter 6200 for more than 2 decades. The justification for using site specific costs, rather than total costs allocated across all sites, is that an individual should only be liable for the room and board the individual receives. If the costs are allocated across all sites, then costs associated with an individual who has a higher level of need, such as an individual who has a special diet, would be shared with other individuals who do not receive the benefit of those additional costs.

Subsection (a) is clarified to specify the actual documented room and board costs at the individual's residential service location.

In supported living, the residential service location is not provider-owned or provider-leased, so §§ 6100.681—6100.694 do not apply. Section 6100.684 does not interfere with or make HUD participation difficult for supported living, since this section does not apply to supported living services. Supported living services may be provided in any setting, regardless of HUD funding.

§ 6100.685—Benefits

A provider association, plus numerous form letters from commentators, ask that the provider be required to notify the representative payee if benefits are received. Another provider association asserts that because utilities are in the provider's name, energy assistance cannot offset expenses for the provider. The provider association also states that the individual is entitled to the rent rebate, so rent rebates should not be part of the provider's expense. In subsection (a), a provider asks that applying for benefits be optional, rather than mandatory. A provider association states that subsection (b) contradicts subsection (c).

Response

Since the individual or the representative payee applies for the benefits, the individual and representative payee are notified by the benefit agency. The Department is uncertain why the provider association asks to mandate additional paperwork.

The concern that a rent rebate may not be retained by the provider is a misunderstanding of how to apply for such benefits. If the application is completed as "group living," the rent rebate or food assistance is retained and used by the provider. This service helps the provider to offset the costs of room and board, if the application is completed accurately. The benefit monies are retained by the provider and must be subtracted from the actual room and board costs for a specific location before calculating the individual's share of room and board.

When applying for a rent rebate as a group living arrangement, other assistance benefits, such as energy assistance, may also be available and should be identified by the county assistance office. These additional benefits could help offset the costs charged to individuals, and, as such, the application for benefits is not optional.

Subsection (c) is clarified to state that the benefits are not considered part of the individual's income.

Subsections (b) and (c) are not contradictory; (b) requires deducting the value of the benefits from the room and board costs, while (c) states that benefits may not be considered as part of the individual's income.

The term "food stamps" is updated to "food and nutrition assistance."

§ 6100.686—Room and board rate

A provider states that proration should not occur until after a period of 2 weeks on leave from the residence to limit the proliferation of administrative work generated by the shorter period. A provider asks to make this provision consistent with the landlord-tenant relationship where no proration of payment occurs. A provider association, plus numerous form letters from commentators, support the change to 8 days; the change from every day to 8 days is an improvement. A few providers ask the Department to set a minimum amount the individual retains as $30. A provider association asks the Department to post the minimum amount retained by the individual in a departmental bulletin.

Response

As supported by the provider association comment, the administrative paperwork is reduced from the current daily proration requirement in § 51.121(d)(2) (relating to room and board) to 8 days in the final-form regulation. While there was one public comment about extending the proration requirement to 2 weeks, discussions with stakeholders support the decision to move from daily to 8 days. The landlord-tenant provision in the proposed § 6100.444 is deleted. Note that only board is prorated; room costs are not prorated.

The minimum amount to be retained by the individual is established by the U.S. Social Security Administration (SSA), so it should not be set in State regulation. While the minimum amount is currently $30, this amount may be changed by the SSA. As requested by the commentator, when the SSA changes the minimum amount to be retained by the individual, the change will be announced to the providers and other affected parties.

A clarification is added to subsections (a) and (b) that the room and board rate is established using the SSI maximum rate, plus the Pennsylvania supplement. This same clarification is also made in § 6100.688 (relating to modifications to the room and board residency agreement).

§ 6100.687—Documentation in proposed rulemaking

A provider association asks to delete this requirement as duplicative.

Response

This section is deleted; the necessary documentation requirement is relocated to § 6100.682(d) (relating to assistance to the individual).

§ 6100.687 (§ 6100.688 in proposed rulemaking)—Completing and signing the room and board residency agreement

An advocacy organization asks to require the use of auxiliary aids and services. A few providers ask to publish the room and board agreement in the chapter. A provider asks not to specify a form since HUD has its own required lease. A few county governments ask if the representative payee for social security benefits or a power of attorney can sign the room and board residency agreement.

Response

Communication is addressed in § 6100.50 (relating to communication). Auxiliary aids and services and language interpreters must be provided if required by the individual. The required room and board residency agreement form will be available to the public, but it will not be published in the chapter to allow for timely adjustments as Federal and State statutes and regulations change. The room and board sections of the final-form regulation do not apply to HUD housing, since HUD housing is not owned or leased by the provider. In subsection (c), a representative payee or a

financial power of attorney may sign the room and board residency agreement; the term "designated person for the individual's benefits" includes any person that the individual designates, including a representative payee. Clarification is added to subsection (c) that if an individual has a designated person for the individual's benefits, the designated person signs the room and board residency agreement.

§ 6100.689 (§ 6100.690 in proposed rulemaking)—Copy of room and board residency agreement

A provider association, plus numerous form letters from commentators, ask to require the provider to give a copy of the agreement to the support coordinator and the representative payee.

Response

The support coordinator does not need a copy of the agreement because the support coordinator is not responsible for the provider's billing of room and board charges. While providing a copy of the agreement to the representative payee who signed the form is recommended, the Department does not believe it is necessary to create a regulatory compliance item for paperwork verification.

§ 6100.690 (§ 6100.691 in proposed rulemaking)—Respite care

A provider association, plus numerous form letters from commentators, ask to explain what "30 days or less" means. A few providers ask to allow the provider to charge a fee to the individual if it is past 30 days, as this is a financial hardship on the provider.

Response

The reference to the time period is deleted. This is not a financial hardship on the provider because the most appropriate service to authorize when an individual is receiving more than 30 days of service in a residential setting is residential habilitation or life sharing. The rates for residential habilitation and life sharing are higher than the respite care rate.

§ 6100.691 (§ 6100.692 in proposed rulemaking)—Hospitalization

A few provider associations, plus numerous form letters from commentators, ask to delete this section or clarify that the Department is responsible for payment after 30 continuous days of absence as this is a financial hardship on the provider. A provider association asserts that if an individual is hospitalized for more than 30 days, the individual is placed in reserved capacity, but the individual's belongings stay in the home and no one else may receive services in that room; the provider association believes that the provider should continue to charge room and board for the room since the space cannot be used. A provider asks to continue to bill for the ineligible portion. A provider asks to make this section consistent with the landlord-tenant provisions. The IRRC asks to address the reasonableness, need for and economic or fiscal impacts of this section.

Response

Allowing the provider to bill for the leave days is of grave consequence to the individuals who do not have the financial resources for payment. After debate and deliberation, the financial concerns expressed by the commentators are addressed in § 6100.55. Section 6100.55 provides financial relief to providers by adjusting the approved program capacity to allow for an increase in the provider's rates for the time period of the individual's medical, hospital or therapeutic leave.

Section 6100.691 (relating to hospitalization), requiring that the provider may not charge room and board after 30 consecutive days of an individual being in a hospital or rehabilitation facility, is retained as necessary and reasonable to protect the individual's resources and assets. The economic

and fiscal impact is minimized with the addition of § 6100.55 that allows an increase in the provider's rates during this period of extended stay at a hospital or rehabilitation facility.

§ 6100.692 (§ 6100.693 in proposed rulemaking)—Exception

A provider association, plus numerous form letters from commentators, ask to add the qualifier "unless the provider is paying for the food/nutritional supplement."

Response

No change is made to the section. The provider is not permitted to pay for the food or nutritional supplements with HCBS funds. "Nutritional supplements" are now part of room and board costs. The Department will either cover the costs with medical assistance funds or, if medical assistance is denied, the provider may request a regulatory waiver to cover the cost of the food or nutritional supplements.

§ 6100.693 (§ 6100.694 in proposed rulemaking)—Delay in an individual's income

The IRRC asks to clarify the meaning of "small amount" to set a measureable standard.

A provider association asks that rent be billed during the time when an individual's income is delayed and to require back rent; the provider association asks to disallow the option of billing rent to an individual without current income.

Response

The term "small amount" is changed to "negotiated amount;" this amount is negotiated between the provider and the individual or person designated by the individual, based on the individual's ability to pay. The provider will work with the individual to determine how much, if any, may be paid until the income source resumes. While the provider must still send a bill, paragraph (1) allows the provider the option to charge no amount or a partial amount until income resumes.

§ 6100.694—Managing individual finances

A university asks to prohibit a provider from charging a fee for managing an individual's finances or for serving as an individual's financial representative. The university asserts that an individual should have access to all of the individual's funds without paying a fee for representative payee support. In addition, the provider should provide support to the individual to manage finances free of charge.

Response

A new provision is added to address the concern of the commentator. Although the SSA allows certain organizations to collect a monthly fee from an individual for expenses incurred in providing financial services, this is not permitted in the HCBS program. This is not a new expense and there is no fiscal impact since providers are reimbursed for managing an individual's finances as part of their rate. Management of the individual's payments guarantees the provider the prompt and reliable collection of room and board payments.

§ 6100.711—Fee for the ineligible portion of residential service

The IRRC asks that similar and appropriate comments that are made to § 6100.571 (relating to fee schedule rates) be made to this section. A provider asks to use identical provisions as in § 6100.571. An advocacy organization asks to assure that ineligible rates, together with contributions from the individual and other benefits, are sufficient to cover the cost of room and board, including wear and tear. A provider association, plus numerous form letters from commentators, ask to delete

this section since § 6100.571 covers this. Comments similar to those regarding § 6100.571, including using the rates reflected by the data and using a market-based approach, including a provision for an application of the Consumer Price Index or Medicare Home Health Market Basket Index, were received. A few providers ask to include a vacancy factor in the residential ineligible fee schedule.

Response

Changes similar to those made in § 6100.571 are made to this section regarding the ineligible portion of residential services. As with the eligible portion of residential services, the ineligible component is developed using the market-based approach explained earlier in this preamble, but the list of factors in subsection (c) differs from § 6100.571(b), since the scope of the fees differ. The proposed factors of service needs of the individuals, staff wages, staff-related expenses and productivity are deleted since they do not apply to the ineligible portion of payment for residential services. Housing costs are the primary rate component of the ineligible portion of residential services. To establish an appropriate rate for the ineligible portion of residential services, the Department examines current Federal housing data to determine housing costs among the Commonwealth counties. In addition, a new factor of meals for staff persons is added. A vacancy factor is included under subsection (c)(1) regarding occupancy.

The Department intends to provide the same public notice and comment period for the final rate-setting methodology for the ineligible portion of the residential services as for the eligible portion of such services.

§ 6100.741—Sanctions

A provider association asks to use the terms "compliance," "remedies" and "remediation" because the terms "enforcement" and "sanctions" are outdated. A provider association and a provider ask to use positive terms aimed at compliance, since these are not licensing regulations.

A provider association, plus numerous form letters from commentators, ask to specify the time period that applies in subsection (b)(1). The same provider association asks to weigh the regulatory violations in subsection (b)(1) so each section does not carry the same weight when enforcing, extend the time frame in subsection (b)(2), as 10 days is too short to develop a meaningful plan, require free and full legal and authorized access in subsection (b)(5) and apply the appeal provisions in Chapter 1101 (relating to general provisions).

Response

The terms "enforcement" and "sanction" are the correct terms when specifying the Department's authority and powers to enforce this chapter. As discussed previously in § 6100.42(e) (relating to monitoring compliance), the term "violation" is changed to "non-compliance." Although governed by different authorizing statutes, as with the Department's licensing regulations, enforcement of Chapter 6100 will occur.

No time period is added in subsection (b)(1); this applies to any non-compliance with this chapter; this does not apply if the Department has verified in writing that a non-compliance is fully corrected. The Department will consider developing a weighted measurement tool and system; however, in order to develop a valid weighting tool, the final-form regulation should be in effect and implemented for several years to gain an understanding of the regulatory compliance relationship between the various sections of the regulation and to determine which sections are more reliable predictors of performance.

No timeline for return of a corrective action plan is prescribed in either the proposed rulemaking or the final-form regulation; the time frame for completing the corrective action plan will be

determined by the Department based on the number and types of non-compliance issues.

The substantive provisions of subsection (b)(5) are not changed; the Department and the designated managing entity have full and free access to the provider's records and the individuals receiving services. There are no statutory or regulatory restrictions or limitations to departmental or designated managing entity access. Denial of access or delaying access may result in a sanction in accordance with § 6100.741.

Applicable appeal procedures are addressed under § 6100.41 (relating to appeals). Specifically, that provision refers to Chapter 41 (relating to medical assistance provider appeal procedures), which incorporates by reference the actions identified as appealable actions. See § 41.3(a) (relating to definitions).

§ 6100.742—Array of sanctions

A provider association, plus numerous form letters from commentators, suggest deletion of paragraph (6); however, no rationale is provided. Another provider association, plus numerous form letters from commentators, ask for a graduated application of sanctions, stating that different sanctions may be effective for different non-compliance issues. The same provider association asks what happens if the provider cannot cover the costs to appoint a master and what types of non-compliance might result in this action.

Response

The Department agrees that different sanctions will be effective in different circumstances and for different types of non-compliance issues. The Department will apply the level of sanction necessary to obtain the desired remedy. In paragraph (6), the appointment of a master can be especially useful for a large provider that has multiple, serious and systemic non-compliance issues related to mismanagement.

§ 6100.743—Consideration as to type of sanction utilized

A provider association, plus numerous form letters from commentators, assert that the Department may not act with a capricious disregard of the facts that underlie a non-compliance issue. The provider association also asserts the Department's consideration of variables in determining a sanction is unsupported in law; the Department wrongly assumes unfettered discretion; and the Department does not have full discretion to take action in an otherwise unregulated environment.

Another provider association asks to delete subsections (a) and (b). A provider asks that the remedy relate to the scope of the infraction. Another provider asks the Department to act consistently and reasonably at all times, based on facts and not discretion.

A provider asks to clarify the appeal process.

The IRRC asks the Department to explain its authority.

Response

Subsection (a) is revised to clarify that the Department may impose one or more of the sanctions in § 6100.742 (relating to array of sanctions), based on the Department's review of the facts and circumstances specified in § 6100.741(b) (relating to sanctions). The decision to vary the sanction based on the facts and circumstances of each case is within the Department's powers and duties. See 62 P.S. § 201(2) of the Human Services Code, providing the Department with broad authority to promulgate regulations, establish and enforce standards. There is no "one size fits all" approach to

enforcement, as supported by the comment by another provider association in § 6100.742, requesting a graduated application of sanctions, stating that different sanctions may be more effective for different types of non-compliance issues. The Department will assess the circumstance of each non-compliance issue and apply the level of sanction necessary to obtain the desired remedy.

Subsection (c) is revised to refer to "factors," rather than "variables," since the term "factors" is more precise and clear. Subsection (c) is further revised to change the term "may" to "will" to require the Department to consider the factors when determining and implementing a sanction or combination of sanctions.

Appeals of sanctions issued in accordance with the final-form regulation are made in accordance with Chapter 41 as specified in § 6100.41 (relating to appeals).

§ 6100.801 (§ 6100.802 in proposed rulemaking)—Adult autism waiver

A university asks to apply all sections of this chapter to the adult autism waiver.

Response

This change is made. There are no exclusions or exceptions for services provided under the adult autism waiver. The few proposed exemptions are no longer necessary or applicable.

§ 6100.802—Agency with choice

Several providers, a family association and an advocacy organization ask to delete an agency with choice (AWC) from the scope of the final-form regulation, arguing that an AWC is similar to the vendor-fiscal model that is exempt. Numerous commentators request additional AWC exemptions, including criminal history checks, communication, the human rights team, reserved capacity, individual residential rights and incident analysis. Other commentators support the requirements for training, rights, individual plans and positive intervention.

A provider asks that an AWC be required to have standardized policies and procedures and that the AWC be transparent in its complaint process.

Numerous commentators, including provider associations, providers, families and advocates, ask to exempt an AWC from staff orientation, annual staff training or both. Reasons for a training exemption include the following: orientation is sufficient, communication with families is more important than formal training, many staff are part-time employees, training creates barriers to flexibility and choice, training is an undue hardship for families, training will reduce service to families, the unit rate does not support training and training must be individualized for each individual.

Response

AWC will continue to be regulated under this chapter. Vendor-fiscal, employer-agent and AWC are distinct types of financial management service providers. The most significant distinction is that the AWC is a co-managing employer model and, as such, the AWC has a primary role in providing quality services and ensuring compliance with basic program requirements, such as incident reporting and individual rights.

The cost for 32 hours of training per participant, per year is included in the AWC rates effective July 1, 2017. This rate increase is intended to cover multiple staff providing various services. AWC staff must complete the orientation in § 6100.142 (relating to orientation); while the core training topics are specified, there are no minimum number of hours required for this orientation.

The following exemptions are added for AWC staff in subsection (b)(3)(i)—(iii): the minimum number of annual training hours, the training course regarding the safe and appropriate use of behavior supports and the training for staff who work fewer than 30 days in a 12-month period.

To provide health and safety protections to the individuals who receive services through an AWC, the general provisions, general requirements, individual rights, individual plan, restrictive procedures and incident management provisions apply.

In response to the comment asking that the AWC be required to have standardized policies and procedures, the Department did not make this change since standardized policies are not required for other HCBS and it would create a potential administrative burden for the AWC. In response to the comment that the AWC be transparent in its complaint process, the complaint procedures in § 6100.51 apply to an AWC.

§ 6100.802 (§ 6100.803 in proposed rulemaking)—Support coordination, targeted support management and base-funding support coordination

A few providers ask the Department to provide the standard support coordinator training course. Under subsection (e)(1), a provider suggests that all the required training cannot be completed in 24 hours. A university asks to require training on person-directed services. A provider association, plus numerous form letters from commentators, ask to include the cost of training in rate setting.

Under subsection (e)(2), commentators ask to explain why the responsibility for a support coordinator is distinguished from the incident reporting expectations of other types of providers under §§ 6100.401—6100.403 (relating to types of incidents and timelines for reporting; incident investigation; and individual needs). Commentators ask if "report" means to file an incident report through the Department's reporting system and with other appropriate State-mandated entities. A university and a few advocacy organizations ask to delete the language that states the support coordinator must report only what the support coordinator observes directly. The university and an advocacy organization assert that the proposed regulation places individuals at significant risk; the support coordinator must report all incidents whether the support coordinator observes the occurrence directly or if the incident comes to the support coordinator's attention by any means. A provider association, plus numerous form letters from commentators, support the provision as proposed that requires a support coordinator to report only those incidents he observes directly.

The IRRC asks to clarify where and how the reporting will be done. The IRRC asks to explain the reasonableness of setting the responsibilities for a support coordinator apart from the expectations for other providers.

Under subsection (e)(3) in proposed rulemaking, a county government suggests that a 6-month review is too frequent. The IRRC asks to address the reasonableness of this provision.

A provider asks to ensure the standards for individual plans are consistent across all support coordination agencies.

A university and an advocacy organization ask to require the support coordinator to meet with the individual at least quarterly to complete a wellness check and assure that services are provided in accordance with the individual plan.

Response

The Department will continue to provide the mandated training courses for support coordinators. While the Department understands that teaching the training material for the required areas may take more than 24 hours, the length of the training course is at the discretion of the support coordination agency based on the needs of the support coordinator. For example, a veteran support

coordinator may be able to take an abbreviated course to refresh on the material previously learned. Training on the application of person-centered approaches is required for a support coordinator under §§ 6100.142 and 6100.143 (relating to orientation; and annual training). The cost of staff training for a support coordinator is included in the fee schedule rates.

Subsection (e)(2) is revised to require a support coordinator, targeted support manager and a base-funding support coordinator to report all incidents, unless the incident was already reported and documented by another source. For example, if an incident has already been reported by a staff person to the Department and to other required reporting entities, and the support coordinator verifies that the incident has been properly reported, it is unnecessary for the support coordinator to reenter the incident report. There are no differences in the reporting requirements for a support coordinator and a staff person working in another type of service. The support coordinator reports an incident through the Department's online information management system. In response to the question from the IRRC about the reasonableness of setting the responsibilities for support coordinators apart from the expectations for other providers, the Department has amended this section to require that the responsibilities for reporting incidents are the same for all providers.

The requirements in proposed subsection (e)(3) and (e)(4) regarding documentation of continued need and enhanced staffing are deleted as unnecessary and overly prescriptive. These assessment areas are adequately covered in the individual plan process.

The requirements for the content of individual plans as specified in § 6100.223 apply to all support coordination agencies.

The duties of the support coordinator regarding the individual plan are specified in § 6100.225. An annual review of the individual plan is required at a minimum. Additional individual plan reviews are required when there is a change in the individual's needs. A specific requirement for a quarterly wellness check for each individual is not added because the needs of each individual vary greatly.

§ 6100.803 (§ 6100.804 in proposed rulemaking)—Organized health care delivery system

Several providers and a family ask to exempt an organized health care delivery system (OHCDS) from this chapter, asserting that the regulations apply only to licensed providers.

Numerous commentators request additional OHCDS exemptions, including criminal history checks, the human rights team, reserved capacity, individual rights and incident management. Other commentators support the requirements for training, rights, individual plans and positive intervention.

Numerous commentators, including a provider association, plus numerous form letters from commentators, providers, families and advocates, ask to exempt vendors from staff orientation, annual staff training or both.

Response

The final-form regulation applies to both licensed and unlicensed providers that provide HCBS or base-funding only services. While an OHCDS must be regulated under this chapter to protect the health and safety of the individuals receiving HCBS, upon reconsideration of this special program, the Department is exempting an OHCDS from the criminal history checks for public transportation and indirect services, training, incident analysis and medication administration requirements because an OHCDS purchases goods or services approved in an individual's plan from generic community businesses, such as public transit, retail stores and general contractors for home adaptations, and does not directly provide the services.

§ 6100.804 (§ 6100.805 in proposed rulemaking)—Base-funding

A provider association supports the application of this chapter, with the exceptions specified in § 6100.804, to base-funding only services.

Response

The Department appreciates the comment supporting the application of Chapter 6100 to base-funding services, with the exceptions specified in § 6100.804. The application of Chapter 6100 to based-funding only services, with the noted exceptions, provides equitable health and safety protections for the individuals across the ODP service system, while making it easier for an individual to transition through the various funding mechanisms.

The Department added subsection (b)(6) to clarify that the section on transition applies to base-funding only services, because transition is an important function of base-funding only services when an individual transitions from one funding source to another funding source.

§ 6100.805 (§ 6100.806 in proposed rulemaking)—Vendor goods and services

A provider asks to exempt vendors from this chapter, asking that the Department regulate and monitor vendors outside of regulation.

A few providers and an advocacy organization ask to exempt vendors from annual staff training. Numerous commentators request additional vendor exemptions, including criminal history checks, human rights team, reserved capacity, individual rights and incident analysis.

Several providers ask how this requirement will be applied to respite camps. An advocacy organization, a family group and a provider ask to exempt families who must make a down payment or pay a fee prior to service delivery at a respite camp.

Response

The final-form regulation applies to vendor goods and services; there is no alternate method to require and enforce compliance except through regulation. While vendor goods and services must be regulated under this chapter to protect the health and safety of the individuals receiving HCBS, upon reconsideration of this special program, the Department is exempting vendors from the criminal history checks for public transportation and indirect goods and services.

Broad vendor exemptions from the requirements for criminal history checks, human rights team, reserved capacity, individual rights and incident analysis are not added, because these provisions are important health and safety protections for the individuals since certain vendors provide direct services to individuals.

Regarding the request to clarify how the regulation applies to respite camps, the sections regarding individual plans, individual rights, restrictive procedures, incident management and medication administration apply only to non-integrated respite camps that serve 25% or more people with disabilities.

Regulatory Review Act

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on August 24, 2018, the Department submitted a copy of the notice of proposed rulemaking, published at 46 Pa.B. 7061, to IRRC and the Chairpersons of the House and Senate Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the House and Senate Committees were provided with copies of the comments received during the public comment period, as well as

other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on October 17, 2018, the final-form rulemaking was approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 18, 2018, and approved the final-form rulemaking.

Findings

The Department finds that:

(a) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(b) The adoption of this final-form rulemaking in the manner provided by this order is necessary and appropriate for the administration and enforcement of sections 201(2), 403(b), 403.1(a) and (b), 911 and 1021 of the Human Services Code and section 201(2) of the Mental Health and Intellectual Disability Act of 1966.

Order

The Department acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 55 Pa. Code Chapters 51, 2380, 2390, 6100, 6200, 6400 and 6500, are amended by adding §§ 2380.26, 2380.37—2380.39, 2380.166—2380.169, 2390.24, 2390.48, 2390.49, 2390.171—2390.180, 2390.191—2390.198, 6100.1—6100.3, 6100.41—6100.56, 6100.81—6100.85, 6100.141—6100.143, 6100.181—6100.186, 6100.221—6100.227, 6100.261, 6100.262, 6100.301—6100.307, 6100.341—6100.350, 6100.401—6100.405, 6100.441—6100.445, 6100.461—6100.469, 6100.481—6100.485, 6100.571, 6100.641—6100.672, 6100.681—6100.694, 6100.711, 6100.741—6100.744, 6100.801—6100.805, 6400.24, 6400.25, 6400.50—6400.52, 6400.207—6400.210, 6500.25, 6500.26, 6500.48, 6500.49, 6500.139 and 6500.177—6500.180 and deleting §§ 51.1—51.4, 51.11—51.17, 51.17a, 51.18—51.34, 51.41—51.48, 51.51—51.53, 51.61, 51.62, 51.71—51.75, 51.81—51.103, 51.111, 51.121—51.128, 51.131, 51.141, 51.151—51.157, 2380.124, 2380.157—2380.165, 2380.187, 2390.157, 6200.1—6200.3, 6200.3a, 6200.11—6200.20, 6200.31—6200.35, 6400.164, 6400.187, 6400.197—6400.206, 6500.46, 6500.134, 6500.157 and 6500.167—6500.176 and amending §§ 2380.3, 2380.17—2380.19, 2380.21, 2380.33, 2380.35, 2380.36, 2380.121, 2380.122, 2380.123, 2380.125, 2380.126, 2380.127—2380.129, 2380.152, 2380.154—2380.156, 2380.173, 2380.181—2380.186, 2380.188, 2390.5, 2390.18, 2390.19, 2390.21, 2390.33, 2390.39, 2390.40, 2390.124, 2390.151—2390.156, 2390.158, 6400.1—6400.3, 6400.4, 6400.15, 6400.18—6400.20, 6400.31—6400.34, 6400.44—6400.46, 6400.161, 6400.162, 6400.163, 6400.165, 6400.166, 6400.167—6400.169, 6400.181—6400.186, 6400.188, 6400.192—6400.196, 6400.213, 6500.1—6500.4, 6500.15, 6500.17, 6500.20—6500.22, 6500.31—6500.34, 6500.41—6500.45, 6500.47, 6500.69, 6500.76, 6500.131, 6500.132, 6500.133, 6500.135, 6500.136, 6500.137, 6500.138, 6500.151—6500.156, 6500.158—6500.161, 6500.164—6500.166, 6500.182, 6500.183 and 6500.185 to read as set forth in Annex A of this order.

(*Editor's Note*: Sections 2380.124 and 6500.46 were proposed to be amended in the proposed rulemaking published at 46 Pa.B. 7061 and are now being reserved in this final-form rulemaking.)

(*Editor's Note*: Sections 2380.151, 2380.153, 6400.191, 6500.162 and 6500.163 were proposed to be amended; however, these amendments have been withdrawn in this final-form rulemaking.)

(*Editor's Note*: Sections 2380.166—2380.169, 2390.177—2390.180, 6100.56, 6100.227, 6400.25, 6400.207—6400.210, 6500.26 and 6500.177—6500.180 were not part of the proposed rulemaking published at 46 Pa.B. 7061 and are being added as new in this final-form rulemaking.)

(*Editor's Note*: Sections 2380.188, 2390.158, 6400.188 and 6500.158 were proposed to be reserved; however, these sections are being amended in this final-form rulemaking.)

(*Editor's Note*: Proposed § 2390.194 is not being adopted in this final-form rulemaking; therefore, §§ 2390.195—2390.199 have been renumbered as §§ 2390.194—2390.198 and § 2390.199 is not included in this final-form rulemaking.)

(*Editor's Note*: Proposed §§ 6100.144 and 6100.263 are not being adopted in this final-form rulemaking.)

(*Editor's Note*: Proposed § 6100.85 is not being adopted in this final-form rulemaking; therefore, § 6100.86 has been renumbered as § 6100.85 in this final-form rulemaking.)

(*Editor's Note*: Proposed §§ 6100.341—6100.345 have been replaced with new text and new §§ 6100.346—6100.350 have been added in this final-form rulemaking.)

(*Editor's Note*: Proposed §§ 6100.444 and 6100.445 are not being adopted in this final-form rulemaking; therefore, proposed §§ 6100.446 and 6100.447 have been renumbered as §§ 6100.444 and 6100.445, respectively.)

(*Editor's Note*: Proposed § 6100.464 is not being adopted in this final-form rulemaking; therefore, proposed §§ 6100.465—6100.470 have been renumbered as §§ 6100.464—6100.469, respectively.)

(*Editor's Note*: Proposed § 6100.483 is not being adopted in this final-form rulemaking; therefore, proposed §§ 6100.484 and 6100.485 are being renumbered as §§ 6100.483 and 6100.484. Additionally, proposed § 6100.486 is not being adopted in this final-form rulemaking; therefore, proposed § 6100.487 is being renumbered as § 6100.485.)

(*Editor's Note*: Proposed § 6100.687 is not being adopted in this final-form rulemaking; therefore, proposed §§ 6100.688—6100.694 are being renumbered as §§ 6100.687—6100.693 and a new § 6100.694 is included in this final-form rulemaking.)

(*Editor's Note*: Proposed § 6100.801 is not being adoptedin this final-form rulemaking; therefore, §§ 6100.802—6100.806 are being renumbered as §§ 6100.801—6100.805.)

(b) The Secretary of the Department shall submit this order and Annex A to the Offices of General Counsel and the Attorney General for approval as to legality and form as required by law.

(c) The Secretary of the Department shall certify and deposit this order and Annex A with the Legislative Reference Bureau as required by law.

(d) This order shall take effect upon publication for §§ 6100.55, 6100.226, 6100.227, 6100.481—6100.485, 6100.571, 6100.641—6100.672, 6100.741—6100.744, 6100.801, 6100.803 and 6100.805; on March 17, 2019, for § 6100.444(c), and 120 days following publication for all other sections of this final-form rulemaking.

TERESA D. MILLER,
Secretary

(*Editor's Note*: See 48 Pa.B. 7085 (November 3, 2018) for IRRC's approval order.)

Fiscal Note: Fiscal note ID # 14-540 remains valid for the final adoption of the subject regulations.

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