

Comments of the Independent Regulatory Review Commission



Department of Human Services Regulation #14-540 (IRRC #3160)

Home and Community-Based Supports and Licensing

January 18, 2017

We submit for your consideration the following comments on the proposed rulemaking published in the November 5, 2016 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Human Services (Department) to respond to all comments received from us or any other source.

1. Statutory authority; Determining whether the regulation is in the public interest; Economic or fiscal impacts; Protection of the public health, safety and welfare.

Section 5.2 of the RRA (71 P.S. § 745.5b) directs the Independent Regulatory Review Commission (Commission) to determine whether a regulation is in the public interest. When making this determination, the Commission considers criteria such as economic or fiscal impacts and reasonableness. To make that determination, the Commission must analyze the text of the Preamble and proposed regulation and the reasons for the new or amended language. The Commission also considers the information a promulgating agency is required to provide under Section 5 of the RRA (71 P.S. § 745.5(a)) in the regulatory analysis form (RAF).

The explanation of the regulation in the Preamble and the information contained in the RAF are not sufficient to allow the Commission to determine if the regulation is in the public interest. We note the following examples:

- In response to #9 of the RAF, the Department states that home and community-based services (HCBS) provisions are mandated by 42 CFR Part 441. The Department should clarify which subpart is applicable. Additionally, commentators assert that the Department does not address applicable federal and state statutes and case law that prescribe the requirements that the Department must adhere to in establishing payment rates for HCBS services.
- In response to #18, the Department notes that this proposed regulation only provides benefits; it does not acknowledge any adverse effects. However, commentators assert the breadth and number of the proposed regulations appear to create a more cumbersome system, such as the proposed training requirements which will create impractical obligations for certain individuals.

- In response to #19, the Department does not provide a “specific estimate of the costs and/or savings” to the regulated community associated with compliance. Commentators state that the proposed regulations appear to have significant fiscal impacts to certain providers. For example, one commentator asserts that Section 6100.45(b) and (d) (relating to quality management) will cost the provider \$27,000 for a part-time staff position in order to comply. Another commentator submitted costs related to training under Section 6100.143 (relating to annual training).
- In response to #20 and #21, the Department states there will be no or negligible costs for local and state governments, but commentators state that the need to ensure compliance for additional regulations would only increase costs.
- In response to #22, the Department did not address or include copies of forms or reports which are required by Section 5(a)(5) of the RRA. We ask the Department to submit all forms with the RAF of the final regulation.

In the Preamble and RAF submitted with the final-form rulemaking, the Department should provide more detailed information required under Section 5 of the RRA (71 P.S. § 745.5(a)), including a description of the amendments proposed for each section of each chapter of the regulation, why the amendments are required, and any cost impacts of the changes.

Additionally, in the Preamble, the Department states that it is amending Chapters 2380, 2390, 6400 and 6500 to mirror proposed Chapter 6100 in areas of training, rights, person-centered support planning, incident reporting, positive intervention and medication administration. While we acknowledge the Department’s extensive efforts to amend and align the chapters, they do not reflect one another exactly. For example, Chapters 2380, 2390, 6400 and 6500 do not contain sections that mirror Section 6100.404 (relating to final incident report). Further, commentators assert that the Department uses inconsistent terminology between chapters. We ask the Department to explain where and why the chapters are different in the final Preamble.

2. RRA Section 2 – Reaching of consensus.

Section 2 of the RRA (71 P.S § 745.2) explains why the General Assembly felt it was necessary to establish a regulatory review process. Given the interest this proposed regulation has generated, we believe it is appropriate to highlight the following provision of Section 2(a) of the RRA. The provision states, “To the greatest extent possible, this act is intended to encourage the resolution of objections to a regulation and the reaching of a consensus among the commission, the standing committees, interested parties and the agency.”

The Department is to be commended for convening numerous meetings with various stakeholder groups. While these meetings may have been useful in developing this proposed regulation, hundreds of comments were submitted highlighting numerous and significant outstanding concerns among the various parties. In particular, we note the issue of children.

Children would use the facilities and services provided under Chapters 6100, 6400 and 6500; however, children are not addressed in the RAF, Preamble or the proposed regulation.

Commentators assert that, as written, the regulations are oriented toward adults. 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 parent or guardians of minor children, preadmission determinations and planning, education, and coordination with other state agencies.

Based on the range of commentators and volume of comments, it seems that the Department's regulatory language has not yet achieved consensus on many issues. We believe the issues raised deserve careful contemplation because the Department's responses will affect approximately 7,140 homes and facilities serving approximately 42,500 individuals, as well as over 900 providers providing support to more than 50,000 individuals with an intellectual disability or autism. While we compliment the Department for its stated intent to reconvene the external stakeholder work group, we encourage the Department to continue its efforts to strike the appropriate balance of protecting the public's health, safety and welfare while addressing the concerns of the regulated community.

3. Definitions. – Clarity and lack of ambiguity.

Within each of the five chapters the Department includes a subsection relating to definitions. However, the Department also includes definitions within other subsections of each chapter. For example, Section 2380.151(c) defines *dangerous behavior* and *positive intervention*. Do these terms have other meanings when used elsewhere in Chapter 2380? We ask the Department to move all definitions that apply throughout a chapter to the appropriate subsection relating to definitions, and move definitions to the beginning of a subsection if the definitions are only applicable there. Additionally, commentators ask that definitions be consistent across the chapters.

Also, the Department has replaced the term *ISP* with *PSP* in each of the five chapters. However, the Department did not define *PSP* beyond "Person-centered Support Plan," which is actually the term that should be defined. We ask the Department to define the term in all of the chapters.

4. Section 2380.33. Program specialist. – Clarity, feasibility and reasonableness.

Commentators state that education and experience requirements for a program specialist should be consistent throughout the chapters. Commentators urge the Department to consider work experience as a qualification. We ask the Department to explain why requirements are not consistent throughout the chapters, and why work experience is not included as a qualification.

These comments apply to the corresponding provisions in **Chapter 2390** and **6400**.

5. Section 2380.35. Staffing. – Clarity, feasibility and reasonableness.

Subsection (a) requires a minimum of one direct service worker for every six individuals present at a facility, but Subsection (c) requires a minimum of two staff person to be present. We ask the Department to explain these conflicting requirements.

6. Section 2390.151. Assessment. – Clarity, feasibility and reasonableness; Need.

Commentators assert that a full assessment may not be necessary when revising the PSP. We ask the Department to revise this section to clarify when the need exists for a full assessment and for a partial assessment. We ask the Department to explain the reasonableness of the requirement in the Preamble to the final-form regulation.

This comment applies to the corresponding sections in **Chapters 2380, 6400 and 6500.**

7. Section 2390.153. The PSP team. – Clarity, feasibility and reasonableness; Need.

In Subsection (b), the Department requires that three members of the PSP team, in addition to the individual and persons designated by the individual, shall be present at a meeting at which the PSP is developed or revised. Commentators question the need for and practicality of the three-person requirement. We ask the Department to explain the reasonableness of this requirement in the Preamble to the final-form regulation.

8. Chapter 6100. – Conforms to the intention of the General Assembly; Clarity, feasibility and reasonableness.

Commentators assert that as written, this chapter does not address potential conflicts between duly promulgated regulations and the provisions within the federal waivers. Commentators state that it is essential that the intended mandatory provisions of the federal waivers be reflected in the regulation consistent with the requirements of state statute and applicable case law. We ask the Department to address these concerns and ensure that the final regulation conforms to the intent of the General Assembly and sets clear compliance standards for the regulated community.

We further address these concerns relating to the General Payment and Fee Schedule provisions in **Chapters 6100.481—6100.647** in comments 46 and 48.

9. Section 6100.42. Monitoring compliance. – Clarity, feasibility and reasonableness; Need.

In Subsection (e), we ask the Department to explain why corrective action is needed for an “alleged” violation.

10. Section 6100.43. Regulatory waiver. – Clarity, feasibility and reasonableness.

Subsection (f) states that if the request for a waiver involves the immediate protection of an individual’s health and safety, the provider must provide a written copy of the waiver request to the affected individuals and their designees at least 24 hours prior to the submission of the request for a waiver, allowing at least 20 hours for review and comment to the provider, the designated managing entity and the Department. Commentators ask the Department either to add an exception or to revise the section to allow a “presumption of waiver” with a follow-up to formally secure the waiver. We ask the Department to explain the feasibility and reasonableness of the waiver requirement.

11. Section 6100.45. Quality management. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need.

Under Subsection (b), the Department requires providers to review performance data in nine areas. Commentators assert the requirements such as reviewing progress toward outcomes, analysis of successful learning and satisfaction surveys, included in Paragraphs (1), (6) and (7) respectively, will require additional staff time doing paperwork.

Subsection (d) requires the provider to review and document progress on the quality management plan quarterly. A commentator states that mandating performance data review in all nine areas will cost the provider \$27,000 for a part-time staff position as they do not currently have the manpower to monitor quarterly and evaluate the data in all areas listed under Subsection (b).

We ask the Department to explain the reasonableness of and need for the quality management review requirements in the RAF and Preamble to the final-form regulation, and to address the economic impacts of any resulting additional staff time required to comply with quality management provisions.

12. Section 6100.46. Protective services. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness.

“Neglect” and “exploitation” are included in the types of incidents that need to be reported in Sections 6100.401, 2380.17, 2390.18, 6400.18 and 6500.20. We ask the Department to explain the reasonableness of not including “neglect” and “exploitation” in this section, and how this provision protects the public health, safety and welfare.

In Subsection (b), did the Department take into account other possible outcomes of an investigation, such as inconclusive or unconfirmed? Additionally, Subsection (b) restricts direct contact between a staff person, consultant, intern or volunteer and an individual during an abuse investigation. Did the Department consider restricting the staff person, consultant, intern or volunteer from having direct contact with any individual? We ask the Department to explain the reasonableness of the final-form regulation, and how it protects public, health, safety and welfare.

13. Section 6100.47. Criminal history checks. – Protection of the public health, safety and welfare; Clarity and lack of ambiguity.

In Subsection (b), we ask the Department to define “household members” in the final regulation.

Subsection (d) states that this section does not apply to natural supports. The regulation defines *natural support* as an activity or assistance that is provided voluntarily to the individual. Since Subsection (d) applies to an “activity” or “assistance,” it is unclear who the Department intended to exclude under this subsection. We ask the Department to clarify this section through revising the definition of *natural support*, revising the language of the provision, or both. Additionally,

the Department should ensure that the language of the final-form regulation makes clear who is exempt from criminal history checks under this subsection.

14. Section 6100.51. Grievances. – Clarity, feasibility and reasonableness.

Under Subsection (h), we ask the Department to explain why it believes that 21 days from the date the grievance was received is a reasonable amount of time to resolve it.

15. Section 6100.52. Rights team. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures; Need.

Some commentators, while supportive of the concept of a Rights Team, believe that it is already appropriately addressed in the incident management process (Section 6100.401(a)(15) and similar sections in Chapters 2380, 2390, 6400 and 6500). Some commentators assert that this section imposes an unnecessary bureaucratic layer on providers and families, and that the proposed additional administrative duties are inefficient and their associated costs are unnecessary. We ask the Department to explain in the Preamble to the final-form regulation the need for and reasonableness of this section. We also ask the Department to address in the RAF and Preamble any additional costs and paperwork that are likely to result from this new provision.

Commentators state that the expectations contained in Subsection (b)(2)(ii) and(iii) appear to be beyond the scope of the rights team. In addition, they also comment that Subparagraph (2)(iii) needs to reflect the reality that a rights team cannot be expected to resolve certain behaviors which may be directly linked to a particular disability. We ask the Department to explain the reasonableness of these provisions in the Preamble to the final-form regulation.

Under Subsection (f), does the rights team need to meet every three months if there are no incidents?

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

16. Section 6100.53. Conflict of interest. – Clarity, feasibility and reasonableness.

Under Subsection (c), should a person serving on the governing board who is a friend or family member need to disclose the relationship?

17. Section 6100.54. Recordkeeping. – Clarity, feasibility and reasonableness.

The Department should clarify how and where the records will be maintained under Subsection (d).

18. Section 6100.141. Annual training plan. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness.

This section requires the provider to design an annual training plan based on the needs of the individuals as specified in the individuals' PSPs, provider's quality management plan and other data indicating training needs. Commentators assert that the training plan, by definition, is unique to the individual, and as proposed, the regulation is overly prescriptive. Commentators state that more flexibility is needed to accommodate the needs of each individual. We ask the Department to explain the feasibility and reasonableness of these requirements, and how they adequately protect the public health, safety and welfare.

This comment applies to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

19. Section 6100.142. Orientation program.

Section 6100.143. Annual training. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need.

These sections require certain persons, within 30 days after being hired or starting to provide support to an individual, to complete an orientation program. Commentators submitted numerous comments including:

- This mandate adds unnecessary costs as it applies to persons who will rarely or never be involved in direct service to the individual;
- By including consultants in both the orientation program and the annual training, it appears that consultants would need to complete trainings for every provider with whom they consult;
- The Department should explain how requiring clinicians who are classified as consultants to undergo training in Section 6100.143(b) (relating to annual training) is reasonable and necessary;
- This requirement of 12 hours of training annually for fiscal, dietary, housekeeping, maintenance and ancillary staff would add an additional cost of \$13,800; and
- Current rates do not support the increase in training requirements for unlicensed services, with one provider estimating an additional \$36,000 in costs to provide 24 hours of training to 77 contract staff persons.

We ask the Department to explain in the Preamble of the final-form regulation how these sections relate to all services, provider types and service delivery models, and the need for and reasonableness of final-form training requirements. Additionally, we ask the Department to address any economic or fiscal impacts of training requirements in the final-form RAF and Preamble.

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

20. Section 6100.182. Rights of the individual. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness.

Subsection (g) states that an individual has the right to control the individual’s own schedule and activities. Commentators question how this provision aligns with the Department’s proposed plan for services to be in the community 75 percent of the time. We ask the Department to explain in the Preamble to the final regulation the feasibility of this requirement.

This comment applies to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

21. Section 6100.183. Additional rights of the individual in a residential facility. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Subsection (a) allows individuals to have scheduled and unscheduled visitors, and to communicate and meet privately with persons of the individual’s choice, at any time. What happens if someone is injured or abused by a visitor that the provider “allowed” to be alone with the individual? We ask the Department to clarify how provider liability will be handled in this type of scenario. Additionally, we ask the Department to explain in the Preamble how the final-form regulation adequately protects the public health, safety and welfare.

Subsection (d) gives the individual the right to manage and access his/her own finances. How will this provision be implemented if an individual has a representative payee (person who has control over how the individual spends their money)?

Subsection (g) grants an individual the right to lock his/her bedroom door. Several commentators have expressed concern that a locked door could pose a health and safety risk by restricting access. In the Preamble to the final regulation, we ask the Department to explain how this provision protects the health, safety and welfare of individuals in residential facilities.

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

22. Section 6100.184. Negotiation of choices. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Subsection (b) states that choices shall be negotiated by the affected individuals in accordance with the provider’s procedures for the individuals to resolve differences and make choices. What happens when negotiations fail? We ask the Department to clarify how failed negotiations are to be handled, including who makes the ultimate decision and how this section is to be documented to demonstrate compliance.

This comment applies to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

23. Section 6100.185. Informing of rights. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Did the Department consider requiring providers to inform individuals about how they may report when their rights are not being followed?

This comment applies to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

24. Section 6100.186. Role of family and friends. – Economic or fiscal impacts; Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Commentators are concerned that this section implies that the provider is required to make all accommodations necessary without any acknowledgement of feasibility or reasonableness. They assert that the proposed language does not address who determines what is necessary or when it is necessary. We ask the Department to explain in the RAF and Preamble to the final-form regulation the reasonableness, feasibility and economic impacts of the requirements of this section.

25. Section 6100.221. Development of the PSP. – Economic or fiscal impacts; Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Commentators ask the Department to define the terms *service implementation plan*, *supports coordinator* and *targeted supports coordinator*. We agree and ask the Department to define the terms in the final regulation.

Subsection (d) requires the initial PSP to be developed prior to the individual receiving a reimbursed support. Commentators note that this subsection is not consistent with language in the corresponding Chapters 2380.182, 2390.152, 6400.182 and 6500.152. Why is the language inconsistent with provisions in the corresponding licensing chapters?

Subsection (e) requires the PSP to be revised when the individual's needs or support system changes and upon the request of an individual. Should a PSP also be revised annually, as well as at the request of the guardian or a team member?

Subsection (f) states that the initial PSP and PSP revisions must be based upon a current assessment. Commentators seek clarity from the Department as to what areas are required in the assessment and who is responsible for completing the assessment. We ask the Department to clarify the requirements of this subsection, and to address any economic or fiscal impacts on the regulated community.

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

26. Section 6100.222. The PSP process. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Implementation procedures.

We ask the Department to clarify who is responsible for the PSP process, how providers will demonstrate compliance with Paragraph (b)(5), and which guidelines are being referenced in Paragraph (b)(9).

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

27. Section 6100.223. Content of the PSP. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Implementation procedures; Need.

Paragraph (11) requires that the PSP must include “active pursuit of competitive, integrated employment as a first priority, before other activities or supports are considered.” We ask the Department to explain how this provision supports the concept of a “person-centered” support plan.

Commentators ask that Paragraph (17) relating to “excluded, unnecessary or inappropriate supports” be deleted. If the Department keeps the provision in the final-form regulation, we ask the Department to explain the need for and reasonableness of the requirement.

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

28. Section 6100.226. Documentation of support delivery. – Clarity, feasibility and reasonableness; Implementation procedures.

Subsection (c) requires the provider to document support delivery **each time** a support is delivered. Does the Department intend for documentation to occur in every instance of support? We ask the Department to clarify this requirement, including whether documentation of support delivery relates to the amount, frequency and duration, or to units. Also, how this would apply to group home living?

In Subsection (f), we ask the Department to clarify from what date the three-month review is determined.

29. Section 6100.261. Access to the community. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Implementation procedures.

In Subsection (b), the term “ongoing” is subjective. We ask the Department to define the term to set a measurable standard or delete it.

In Subsection (c), we ask the Department to clarify how providers will determine that an individual is being “afforded the same degree of community access and choice as an individual who is similarly in the community, who does not have a disability and who does not receive an HCBS.” What are the standards the regulated community is expected to meet?

30. Section 6100.304. Written notice. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Under Subsection (b), commentators suggest that language be inserted to: (1) allow transitions to occur sooner if agreed to by both parties; and (2) account for emergency situations where an individual's immediate health and safety may be at risk or where the individual's actions could be an immediate health and safety issue for other program participants. We ask the Department to revise the final-form regulation to address these concerns.

31. Section 6100.342. PSP. – Clarity, feasibility and reasonableness; Implementation procedures.

Under Paragraph (2), commentators ask the Department to define "functional analysis" and clarify who is responsible for completing the functional analysis. We ask the Department to clarify in the final regulation how these requirements are to be implemented.

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

32. Section 6100.343. Prohibition of restraints. – Protection of public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Should the Department add an exclusion for doctor-prescribed mechanical restraints not addressed in Subparagraphs (5)(i) and (ii)?

33. Section 6100.344. Permitted interventions. – Clarity, feasibility and reasonableness; Implementation procedures.

Are the provisions in Subsections (c) and (g) redundant?

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

34. Section 6100.401. Types of incidents and timelines for reporting. – Economic or fiscal impacts; Protection of public health, safety and welfare; Clarity, feasibility and reasonableness; Need.

Subsection (a) requires the provider to report certain alleged incidents and suspected incidents through the Department's information management system within 24 hours of discovery by a staff person. Commentators express concern that this section, as proposed, significantly expands the number and type of investigations that would be required to be investigated and adds significant cost without data demonstrating the need to expand the types of incidents requiring investigation. We ask the Department to explain in response to RAF #28 (relating to data) and the Preamble to the final regulation the reasonableness of and need for the expanded reporting list, and to address the economic or fiscal impacts of the additional requirements.

Additionally, commentators ask the Department to remove Paragraphs (13) and (16) from the list because these types of incidents are currently reported within 72 hours of discovery. What is the

need to include these incidents for reporting under this provision if they are already being reported elsewhere?

Subsection (b) seems to require that an individual be notified of an incident relating to him or herself. Also, the Department's expectation in requiring "immediate" notification is unclear. Within what length of time is notification considered immediate? We ask the Department to clarify this provision in the final regulation, and to ensure that notification requirements are reasonable and clear for the regulated community to comply.

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

35. Section 6100.402. Incident investigation. – Economic or fiscal impacts; Protection of the public, health, safety and welfare; Clarity, feasibility and reasonableness.

Based on commentator concerns, we ask the Department in Subsection (a) to define "incident," "alleged incident" and "suspected incident," or to explain in the Preamble why definitions are not necessary.

Commentators state that Subsections (b) and (c) taken together seem to require that every incident must be investigated by a Department-certified incident investigator since it specifically refers to Section 6100.401(a) without exclusion. Is this the Department's intent for this section?

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

36. Section 6100.405. Incident analysis. – Economic or fiscal impacts; Protection of the public, health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Commentators ask if the provisions under Subsections (b) and (e) are already required under quarterly quality management requirements. Commentators ask the Department to explain the reasonableness of a fourfold increase from the current requirement of the annual review. We ask the Department to clarify requirements under this section. We also ask the Department to explain the need for and reasonableness of any increased reporting requirements, and provide an assessment of the economic or fiscal impacts.

These comments apply to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

37. Section 6100.443. Access to the bedroom and the home. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

We ask the Department to clarify how requirements under this Section are to be implemented in the context of potential health and safety risks. For example, in Subsections (d) and (e), who are the "appropriate persons" and "authorized persons" who will have access to individuals' bedrooms and homes? In Subsection (f), is it reasonable or practical to require express

permission for each instance when accessing an individual's bedroom? If express permission is not received, would staff be prohibited from providing the necessary care?

38. Section 6100.444. Lease or ownership. – Protection of the public health, safety and welfare; Clarity and lack of ambiguity; Implementation procedures.

Commentators question the use of the terms “landlords,” “tenants” and “leases” in this section. They assert that the rights conferred in Subsection (a) do not make providers “landlords” or individuals “tenants,” nor do they make their spaces “leased.” Commentators suggest that the Department develop a model or format that can be used to meet requirements and ensure protection of the individual, provider and other residents of a licensed facility. We ask the Department to ensure that the language of this section in the final-form regulation is clear for the regulated community and provides adequate protection of the public health, safety and welfare.

We also ask the Department to clarify whether the “lease” included in this section replaces the room and board agreement required in Section 6100.688 (relating to completing and signing the room and board residency agreement).

39. Section 6100.445. Integration. – Clarity, feasibility and reasonableness; Implementation procedures.

We ask the Department to explain how it and the regulated community are to measure whether an individual has the same degree of community access and choice as an individual who is similarly situated in the community who does not have a disability and who does not receive an HCBS.

40. Section 6100.446. Facility characteristics relating to size of facility. – Economic or fiscal impacts; Protection of public health, safety and welfare; Clarity, feasibility and reasonableness; Need.

The Department proposes to limit the number of persons served by facilities under Subsections (a), (b) and (c). Commentators state that program quality cannot and should not be defined by numbers of persons served. Commentators assert that limiting newly licensed day facilities will dramatically increase the cost per unit/per individual. Did the Department consider making a distinction between program licensing roster capacity and daily attendance capacity? We ask the Department to explain the reasonableness of and need for limiting the number of persons served. We also ask the Department to address in the RAF and Preamble the economic impacts of these limitations on facilities.

41. Section 6100.447. Facility characteristics relating to location of facility. – Economic or fiscal impacts; Protection of public health, safety and welfare; Clarity, feasibility and reasonableness; Need.

Subsection (a) uses the phrase “in close proximity,” which is subjective. We ask the Department to define the phrase, clarify the distance to set a measurable standard or delete the phrase.

Under Subsection (b), commentators state that the Department’s proposed ten percent restriction virtually eliminates housing opportunities for Medicaid Waiver enrollees with non-physical disabilities to live in certain urban communities, and is a profoundly unfunded mandate. How did the Department determine that ten percent is the appropriate limit? We ask the Department to explain in the Preamble the reasonableness of and need for the location restriction. We also ask the Department to address in the RAF and Preamble the economic impacts of these limitations on facilities.

42. Sections 6100.461—6100.470. “Medication Administration” – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness; Implementation procedures.

Commentators submitted concerns related to the Medication Administration provisions in Sections 6100.461—6100.470. Some commentators express concerns about codifying this crucial component of service into regulations. What happens if the codified practices become obsolete as new information and technology emerge? The commentators assert that duplicating content as detail-specific as this proposed regulation across five chapters when Pennsylvania already has an externally-accepted training module invites discrepancy between the regulations and the training manual. For example, commentators state that the required checklist for medication self-administration in the Department’s Approved Medication Administration Training has discrepancies with the proposed regulation. We ask the Department to explain in the Preamble to the final-form regulation how the provisions relating to Medication Administration will account for new information, improved practices and emerging technology while ensuring protection of the public health, safety and welfare.

This comment applies to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

43. Section 6100.462. Medication administration. – Clarity and lack of ambiguity.

In Paragraph (c)(5), what is a prescriber’s “00.163.163” order?

44. Section 6100.465. Prescription medications. – Clarity, feasibility and reasonableness.

Commentators ask the Department to revise Subsection (a) to allow for electronic prescriptions. We ask the Department to amend the language accordingly or explain the reasonableness of requiring the prescription to be in writing.

This comment applies to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

45. Section 6100.469. Medication administration training. – Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness.

In Paragraph (c)(2), we ask the Department to define the term “certified health care professional,” or clarify to whom this term refers.

This comment applies to corresponding provisions in **Chapters 2380, 2390, 6400 and 6500.**

46. Section 6100.481. Departmental rates and classifications. – Statutory authority; Conforms to the intention of the General Assembly; Economic or fiscal impacts; Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness.

Under Section 6100.481(b) the Department states that it will establish a fee by publishing a notice in the *Pennsylvania Bulletin*. What is the Department’s authority for setting fees in this manner? Commentators assert that this provision, read in conjunction with Sections 6100.571(a), (c), (d) and (e), would 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 on in setting the rates, how the factors were actually developed and utilized in setting the rates, and the bases for any assumptions and presumptions relied upon in setting the rates. Commentators further note that under 42 U.S.C. § 1396a(a)(13)(A), the Department must provide public notice of the methodologies that underlie the rates that it proposes to adopt and the justifications used to establish the rates. Additionally, commentators cite to the decision in Christ the King Manor, Inc. v. U.S. Dept. of Human Services, 730 F. 3d 291 (3d Cir. 2013).

It is unclear how or whether there is public input in the Department’s rate-setting process. How is the Department’s approach to setting rates consistent with the decision in the cited court case? How is Subsection (b) consistent with state and federal law? We ask the Department to address these concerns, and to explain in the RAF and Preamble to the final-form regulation how the federal waiver process works and whether a state rulemaking is necessary to establish the rate-setting process.

These comments address similar concerns related to **Section 6100.571** (relating to fee schedule rates) and apply broadly to the general payment and fee schedule provisions in **Chapters 6100.481—6100.647**.

47. Section 6100.486. Bidding. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need for the regulation.

Under Subsection (a), the provider must obtain supplies or equipment using a competitive bidding process. If a provider is paid according to a fee schedule, why should the provider be compelled to obtain bids for services or supplies?

48. Section 6100.571. Fee schedule rates. – Economic or fiscal impacts; Clarity, feasibility and reasonableness.

In Subsection (c), the Department identifies several factors contained in this section that it will “consider” as part of its method for establishing fee schedule rates. The term “consider” is nonregulatory language which does not establish binding norms of general applicability and future effect. This provision should be revised to set clear standards of compliance and provide predictability for the regulation community.

Commentators ask the Department to delete Subsection (c)(7) related to geographic costs because services may be provided outside of the geographic region where the provider's office is located. We ask the Department to explain the reasonableness of including this factor.

These comments apply to corresponding provisions in **Section 6100.711** (relating to fee for the ineligible portion of residential habilitation).

49. Section 6100.648. Donations. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need for the regulation.

In a single payer system which does not reimburse a provider's full allowable cost, why does the Department seek to impose limitations on donations?

50. Section 6100.650. Consultants. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need for the regulation.

Under Paragraph (b)(3), commentators ask why the written agreement with a consultant must include the method of payment, and under Subsection (c), why benefits are not an allowable cost. We ask the Department to explain in the Preamble to the final regulation the need for and reasonableness of these provisions. The Department should also address the economic or fiscal impacts of these provisions.

51. Section 6100.652. Compensation. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need for the regulation.

Under Subsection (b), commentators ask the Department to explain why a bonus or severance payment that is part of a separation package is not an allowable cost. The Department should explain in the Preamble to the final-form regulation why these types of compensation are not an allowable cost. The Department should also address the economic or fiscal impacts of this restriction.

52. Section 6100.661. Fixed assets. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need for the regulation.

Under Subsection (h), commentators state that this provision 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. We ask the Department to explain in the Preamble to the final regulation the reasonableness of and need for this provision. The Department should also address the economic or fiscal impacts of this provision.

53. Section 6100.663. Fixed assets of administrative buildings. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Implementation procedures; Need for the regulation.

Under Subsection (c), commentators ask the Department to state the basis upon which an approval will be granted. How will a provider appeal disapproval of a request for a planned major renovation of an administration building? We ask the Department to clarify these provisions in the final regulation.

Under Subsection (f), some commentators ask the Department to define “funded equity” so that it does not apply to equity built or acquired through donations or fundraising. Other commentators ask for this provision to be deleted entirely. We ask the Department to clarify its intent and explain the reasonableness of the provision in the Preamble to the final regulation.

54. Section 6100.681. Room and board applicability. – Clarity, feasibility and reasonableness.

Commentators assert that this section should only apply to licensed group home settings and not to unlicensed settings or apartment settings. We ask the Department to explain the reasonableness of the provision in the Preamble to the final regulation.

55. Section 6100.692. Hospitalization. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Need for the regulation.

Several commentators recommend that this section be deleted. According to comments received from providers, if an individual is hospitalized for more than 30 consecutive days, they are placed in reserved capacity. Their belongings remain in the home, and the provider is not able to serve someone else in that room. For this reason, providers assert they should be able to continue to charge room/rent for that time period since the space is not able to be used. We ask the Department to explain in the Preamble to the final regulation the reasonableness of and need for this provision. The Department should also address the economic or fiscal impacts of this provision.

56. Section 6100.694. Delay in an individual’s income. – Clarity, feasibility and reasonableness.

Under Paragraph (1), the phrase “small amount” is subjective. We ask the Department to define the phrase to set a measurable standard.

57. Section 6100.743. Consideration as to type of sanction utilized. – Statutory authority; Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness.

Commentators state that the Department’s assertion that it “may” consider “variables” in determining a remedy is unsupported in law. Commentators assert that the Department is duty-bound to act in accordance with facts and does not possess “full discretion” to take any action in

an otherwise regulated environment. We ask the Department to explain in the Preamble to the final regulation its authority relating to types of sanctions.

58. Section 6100.803. Support coordination, targeted support management and base-funded support coordination. – Economic or fiscal impacts; Clarity, feasibility and reasonableness; Implementation procedures.

Under Subsection (e)(2), commentators ask the Department to explain why the responsibility for a supports coordinator is distinguished from the expectations of providers under Sections 6100.401–6100.403. They also ask for clarification of what the term “report” means in this section. Does it mean to file an incident with the current Department reporting system and all other appropriate state-mandated entities? We ask the Department to clarify requirements and implementation procedures for this subsection, and to explain in the Preamble to the final regulation the reasonableness of setting the responsibility of a supports coordinator apart from provider expectations.

Subsection (e)(3) requires that if an individual is authorized for residential habilitation, the support coordinator must review and document the continued need every 6 months. Some commentators remark that six months is too frequent. They also seek clarification from the Department on where and how the reporting will be done. We ask the Department to clarify this provision and explain in the Preamble to the final regulation the reasonableness of the provision.

59. Section 6500.132. Medication administration. – Economic or fiscal impacts; Protection of the public health, safety and welfare; Need for the regulation.

Commentators state that Chapter 6500 service providers are not currently required to complete the Department’s Medication Training Module, which involves approximately six days. They state that this level of intensive training is feasible for Chapter 2380, 2390 and 6400 programs because their staff follows employer-controlled schedules and they have centralized access to administrative supports. We ask the Department to explain the need for and reasonableness of applying these standards to Chapter 6500 programs. The Department also should address any economic or fiscal impacts the requirements will impose.