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Independent Regulatory Review Commission

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DEC 21 2016
Office of Developmental Programs

Julie Mochon
Human Service Program Specialist Supervisor
Office of Developmental Programs
Room 502, Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120

December 16, 2016

Dear Ms. Mochon,

Please accept the enclosed comments on the proposed regulations of 55 PA Code Chapters 6100, 2380, 2390, 6400 and 6500.

As the state reviews comments submitted by providers, families and friends of individuals who will be affected by these regulations, the hope would be that the state give serious consideration to the comments and recommendations and make revisions as appropriate.

Thank you.

Pamela J. Johns

Pamela J. Johns, MA
Policy & Compliance Project Specialist
Barber National Institute
100 Barber Place
Erie, Pennsylvania 16507-1863

Comments on Proposed Chapter 2380 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
	Proposed 2380s	Throughout the proposed 2380s wording of "The facility will..." is used. As many of the tags address items that would be overseen or the responsibility of the provider, would ask that wording reflect such. (example: 2380.17 "The facility shall report...." 2380.18 Incident procedures to protect the individual (a) "....the facility shall review and consider..."; 2380.37 (a) "The facility shall design an annual training plan...."	Revision of wording from "The facility will..." to The provider will....
2380.3	Definitions:	For consistency ask that definitions from 6100s also be included in the 2380s as applicable.	Add definitions from the 6100s that are also applicable to the 2380s
2380.17	Incident report and investigation:	(a) "The provider shall report the following incidents, alleged incidents and suspected incidents through the Department's information management system within 24 hours of discovery by a staff person: (13) Use of a restraint" ; : Currently per 6000.823 Incidents to be reported within 72 hours, includes Medication Error and Restraints. Unclear as to why the state is changing to require these to be reported within 24 hours. This will be a hardship on providers to maintain this added reporting, especially as there are no exceptions. The current reporting system has these as being required within 72 hours not 24.	Ask that Restraints continue to be reported within 72 hours of discovery.
2380.17	Incident report and investigation:	6100.401 (16) "A medication administration error, including prescription and over the counter medication administration errors.": This is not included in 2380.17. Is this an oversight?	Ask for review and consistency across regulations. If medication error is to be added for reporting, would ask it be in the current 72 hour timeframe.
2380.17	Incident report and investigation:	(g) "A Department-certified incident investigator shall conduct an incident investigation of the incident listed under subsection (a)" : This wording sets the requirement that ALL incidents must be investigated. This would be a hardship on large providers to have enough staff certified as an investigator and be able to conduct all the investigations as well as completion of their job responsibilities. Chapter 6000.925 currently identifies categories of incidents that require investigation.	Ask that the current categories of incidents requiring investigation as identified in 6000.925 be maintained in regulation.

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Comments on Proposed Chapter 2380 Regulations
Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2380.21	Individual rights	6100s include various items that are not included in the 2380s, such as : "(g) An individual has the right to control the individual's schedule and activities"; (j) An individual has the right to choose a willing and qualified provider (k) An individual has the right to choose where, when and how to receive needed supports." "(m) An individual has the right to assistive devices and support to enable communication at all times"	Ask for consistency of rights across chapters.
2380.33	Program specialist	It is noted that the 2380s no longer identify a time frame for PSP reviews. Currently 2380.186 (a) reads "The program specialist shall complete an ISP review of the services and expected outcomes in the ISP....with the individual every 3 months or more frequently if..." 2380.33 Program Specialist (b) (2) states "Participating in the PSP process, PSP development, PSP team reviews and the implementation of the PSP in accordance with this chapter? Are 3 month reviews no longer required?	
2380.38	Orientation program:	(a) "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual the following shall complete an orientation program as described in subsection (b)" "(1) Management, program, administrative and fiscal staff persons" "(2) Dietary, housekeeping, maintenance and ancillary staff persons. (5) Paid and unpaid interns who will work alone with individuals (6) Consultants who will work alone with individuals.": The wording of "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual..." is questioned in relation to the inclusion of "administrative and fiscal staff persons"; "housekeeping, maintenance..staff persons" as these staff positions do not provider direct support or service to individuals. For interns and consultants, scheduling of the required training and payment for their hours will be extremely difficult for providers to achieve. Requiring them to complete the outlined orientation training will be difficult to schedule and costly to providers to pay for the training hours.	Remove these positions from the training requirements as they are not appropriate to fulfillment of their job responsibilities.

Comments on Proposed Chapter 2380 Regulations
Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2380.39	Annual training:	(b) The following staff persons shall complete 12 hours of training each year: (3) Consultants who work alone with individuals. (4) Volunteers who work alone with individuals (5) Paid and unpaid interns who work alone with individuals." : As these persons are not true employees of the provider and the required training areas do not necessarily correlate to services they may be providing to individuals. This will cause a burden on providers for scheduling and payment to these persons for their time.	Ask that the number of hours of required training be removed and wording revised to allow for providers to train as appropriate.
2380.121	Medication: Self-administration:	In review of the proposed regulations revisions to current regulation, it is felt that imposing all the identified within regulation will be difficult to maintain and align with the Department's medication administration training which is revised as appropriate based on medical profession changes.	Would ask that regulation mirror the Department's required training and not impose additional restrictions.
2380.121	Medication: Self-administration:	"(a) The facility shall provider an individual who has a prescribed medication with assistance, as needed, for the individual's self-administration of the medication. (b) Assistance in the self-administration of medication includes helping the individual to remember the schedule for taking the medication, offering the individual the medication at the prescribed times, opening a medication container and storing the medication in a secure place." and "(d) The PSP must identify if the individual is unable to self-administer medications. (e) To be considered able to self-administer medications, an individual shall do all of the following:..." : This is a big change from current requirements for self-administration. Assistance of any sort is currently not allowed, so opening this to allow for all this assistance removes some of the independence required for self-administration.	Big change for providers in now allowing for assistance to self-administer. Alignment with self-administration assessments and the Department Medication Training course needs to be maintained.
2380.124	Labeling of medications:	(4)"The prescribed dosage and instructions for administration" (5) "The name and title of the prescriber" : These are new to regulation and out of the control of the provider as labeling comes from the pharmacy filling the prescription.	Would ask this be removed.

Comments on Proposed Chapter 2380 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2380.125	Prescription medications:	(a)"A prescription medication shall be prescribed in writing by an authorized prescriber." (e) "Changes in medication may only be made in writing by the prescriber...? : Do these allow for e-scriptions?	Would ask for rewording for clarification to include e-scribing.
2380.126	Medication records:	Wording change to "Medication record" from "Medication Log". The following are all new to regulations as being required in the medication record. By adding all this required information all medications prescribed to an individual will cause a medication record to increase extensively in size. Time required of staff to document all this will be extensive and take time away from providing direct service to individuals.	Ask that current medication log requirements remain
		(2) "Name and title of the prescriber"	
		(3) "Drug allergies"	
		(5) "Strength of medication"	
		(6) "Dosage form"	
		(7) "Dose of medication"	
		(8) "Route of administration"	
		(9) "Frequency of administration"	
		(10) "Administration times"	
		(11) "Diagnosis or purpose for the medication, including pro re nata"	
		(13) "Name and initials of person administering the medication"	
		(14) "Duration of treatment, if applicable"	
		(15) "Special precautions, if applicable"	
		(16) "Side effects of the medication, if applicable": Unclear if this is referencing inclusion of all potential side effects of a medication, or just those identified by the prescriber to the individual.	

Comments on Proposed Chapter 2380 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2380.126	Medication records:	(c))"If an individual refuses to take a prescribed medication, the refusal shall be documented on the medication record. The refusal shall be reported to the prescriber within 24 hours, unless otherwise instructed by the prescriber. Subsequent refusals to take a prescribed medication shall be reported as required by the prescriber": Contact to the prescriber each time a refusal occurs will cause undue imposition on prescribers. For providers to ask each prescriber for specific instruction regarding notification instructions puts additional requirements and monitoring.	Ask that requirement of notification to the prescriber be removed or re-written such that it reads "As instructed by the prescriber, notification of refusal will be reported."
2380.127	Medication errors:	The 2380s do not identify as 6100.467 (b) identifies that medication errors are to be reported immediately to the prescriber. 2380.127 (b) has the only requirement of "Documentation of medication errors, follow-up action taken and the prescriber's response shall be kept in the individual's record." Lack of the requirements identified in 6100.467 will cause confusion for providers as to what is actually required.	Ask that regulations be consistent across chapters.
2380.151	Positive intervention:	Definitions are given for "Dangerous behavior" and "Positive intervention" within this section.	Ask that all definitions be at the beginning of the chapter.
2380.153	Prohibition of restraints:	There are numerous definitions within this tag that are not in the Definitions section.	Ask that all definitions be at the beginning of the chapter.
2380.153	Prohibition of restraints	2380.153(1) "Seclusion, defined as involuntary confinement of an individual in a room or area from which the individual is physically prevented or verbally directed from leaving" MR Bulletin 00-06-09 page 6 :"Seclusion is not used. Seclusion is defined as placing an individual in a locked room. A locked room includes a room with any type of engaged locking device,, such as a key lock, spring lock bolt lock, foot pressure lock or physically holding the door shut."	Would ask that the definitions that are currently being followed as set forth in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q replace those that are in the proposed regulations to maintain consistency of implementation for providers.
2380.154	Permitted interventions	There are various definitions within this tag that are not in the Definitions section.	Ask that all definitions be at the beginning of the chapter.

Comments on Proposed Chapter 2380 Regulations
Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2380.154	Permitted interventions	(h) "As used in this section , a "physical protective restraint" is a hands-on hold of an individual"	Move this definition to beginning of the chapter with other Definitions and incorporate earlier in this section such as in (b) so readers know what is being talked about.
2380.154	Permitted interventions	(f) "A physical protective restraint may not be used for more than 15 minutes within a 2-hour period" : Putting this time constraint on the used of a physical protective restraint for some individuals will not allow for their health and safety or that of others. Currently MR Bulletin 00-06-09 page 7 "Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per current 55 PA Code 6500.172; 6400.202; 2380.161(d). An individual is immediately released from physical restraint when they no longer present a danger to self or others."	Ask that the time constraint be revised to the current as mandated in MR Bulletin 00-06-09 and current licensing regulations to maintain the health and safety of all individuals.
2380.155	Access to or the use of individuals personal property	"(b) (2)Consent shall be obtained in the presence of the individual, a person designated by the individual and in the presence of and with the support of the support coordinator or targeted support manager" : We acknowledge that we need consent for incidences of restitution however the requirement of all the named parties to be in attendance when the consent is obtained will cause undue burden on providers as an actual meeting will need to be held to have all parties present.	Ask that this be reworded such that the individual in the presence of at least one other person by allowed for the obtainment of the consent

Comments on Proposed Chapter 2380 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2380.156	Rights team:	(c) "Members of the rights team shall include the affected individual, persons designated by the individual, a family member or an advocate appointed by the designated managing entity if the individual is unable to speak for himself, the individual's support coordinator or targeted support manager, a representative from the designated managing entity and a provider representative.": Providers currently follow Chapter 6000 Subchapter Q: Incident Management. A Restrictive Procedure review team already is mandated and is comprised of various members review incidents and restraints. Membership of this the Rights Team in these regulations, to include the individual, persons designated by the individual or designated managing entity, the support coordinator or targeted support manager for EACH individual would be extremely difficult to implement as a provider serving a large number of individuals.	Recommend that the process established under Chapter 6000 Subchapter Q remain as the standard to be implemented..
2380.182	Development of the PSP:	"(c) The support coordinator or targeted support manager <u>or program specialist</u> shall be responsible for the development of the PSP...": Wording varies on this to 6100.221 which states: " (c) The support coordinator, targeted support manager ...." The addition of "or the program specialist" in separate licensing chapters adds confusion as to who is to oversee the development of the PSP.	Would ask that wording be revised to exclude "program specialist" in the 2380 regulations to be consistent with the 6100s.
2380.184	The PSP process	"(1) Provider necessary information and support to ensure that the individual directs the PSP process to the maximum extent possible.": This wording varies from 6100.222 (a) "The PSP process shall be directed by the individual."	Ask that wording between regulations remain consistent to prevent misinterpretation or expectation.

Comments on Proposed Chapter 2390

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
		Throughout the proposed chapter wording used is "The facility..." For most of the items that this wording is now used, it is actually "The provider...." who fulfills the requirement, such as 2390.19 "Incident procedures to protect the individual" ; 2390.40 Annual training plan (a) "The facility shall design an annual training plan...."	Ask that wording be revised or clarified.
2390.18	Incident report and investigation	(a) "The provider shall report the following incidents, alleged incidents and suspected incidents through the Department's information management system within 24 hours of discovery by a staff person: (13) Use of a restraint" ; : Currently per 6000.823 Incidents to be reported within 72 hours, includes Medication Error and Restraints. Unclear as to why the state is changing to require these to be reported within 24 hours. This will be a hardship on providers to maintain this added reporting, especially as there are no exceptions. The current reporting system has these as being required within 72 hours not 24.	Ask that Restraints continue to be reported within 72 hours of discovery.
2390.18	Incident report and investigation:	6100.401 (16) "A medication administration error, including prescription and over the counter medication administration errors.": This is not included in 2390.18. Is this an oversight?	Ask for review and consistency across regulations. If medication error is to be added for reporting, would ask it be in the current 72 hour timeframe.
2390.18	Incident report and investigation:	(g) "A Department-certified incident investigator shall conduct an incident investigation of the incident listed under subsection (a)" : This wording sets the requirement that ALL incidents must be investigated. This would be a hardship on large providers to have enough staff certified as an investigator and be able to conduct all the investigations as well as completion of their job responsibilities. Chapter 6000.925 currently identifies categories of incidents that require investigation.	Ask that the current categories of incidents requiring investigation as identified in 6000.925 be maintained in regulation.

Citation	Caption	Discussion	Recommendation
2390.33	Program specialist	It is noted that the 2390s no longer identify a time frame for PSP reviews. Currently regulations identify reviews to occur every 3 months or more frequently if..." 2390.33 Program Specialist (b) (2) states "Participating in the PSP process, PSP development, PSP team reviews and the implementation of the PSP in accordance with this chapter? Are 3 month reviews no longer required?	
2390.41	Orientation program:	(a) "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual the following shall complete an orientation program as described in subsection (b)" "(1) Management, program, administrative and fiscal staff persons" "(2) Dietary, housekeeping, maintenance and ancillary staff persons. (5) Paid and unpaid interns who will work alone with individuals (6) Consultants who will work alone with individuals.": The wording of "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual..." is questioned in relation to the inclusion of "administrative and fiscal staff persons"; "housekeeping, maintenance..staff persons" as these staff positions do not provider direct support or service to individuals. For interns and consultants, scheduling of the required training and payment for their hours will be extremely difficult for providers to achieve. Requiring them to complete the outlined orientation training will be difficult to schedule and costly to providers to pay for the training hours.	Remove these positions from the training requirements as they are not appropriate to fulfillment of their job responsibilities.

Comments on Proposed Chapter 2390

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2390.42	Annual training	(b) The following staff persons shall complete 12 hours of training each year: (1) Management, program, administrative and fiscal staff persons. (2) Dietary, housekeeping, maintenance and ancillary staff persons. ": Requiring fiscal, dietary, housekeeping and maintenance persons to obtain 12 hours of annual training in the identified areas will be burdensome to providers and these training do not have a direct correlation to their job responsibilities.	Remove these positions from the training requirements as they are not appropriate to fulfillment of their job responsibilities.
2390.42	Annual training:	(b) The following staff persons shall complete 12 hours of training each year: (3) Consultants who work alone with individuals. (4) Volunteers who work alone with individuals (5) Paid and unpaid interns who work alone with individuals." : As these persons are not true employees of the provider and the required training areas do not necessarily correlate to services they may be providing to individuals. This will cause a burden on providers for scheduling and payment to these persons for their time.	Ask that the number of hours of required training be removed and wording revised to allow for providers to train as appropriate.
2390.152	Development of the PSP	"(c) The support coordinator or targeted support manager <u>or program specialist</u> shall be responsible for the development of the PSP...": Wording varies on this to 6100.221 which states: " (c) The support coordinator, targeted support manager ...." The addition of "or the program specialist" in separate licensing chapters adds confusion as to who is to oversee the development of the PSP.	Would ask that wording be revised to exclude "program specialist" in the 2390 regulations to be consistent with the 6100s.
2390.171	Use of positive intervention	Definitions are given for "Dangerous behavior" and "Positive intervention" within this section.	Ask that all definitions be at the beginning of the chapter.
2390.172	Positive intervention: PSP	The 2380 tag does not include " Communication needs" as does tag 6100.342	Ask that there be consistency across regulation chapters.
2390.173	Prohibition of restraints	Definitions are given within this section.	Ask that all definitions be at the beginning of the chapter.

Citation	Caption	Discussion	Recommendation
2390.173	Prohibition of restraints	In this tag definitions of various restraints are given, many of which are newly defined when compared to those currently being followed as per MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q. Of specific concern is the difference between **2390.173 (6)** "A manual restraint, defined as a hands-on physical method that restricts, immobilized or reduces an individual's ability to move his arms, legs, head or other body parts freely, on a nonemergency basis, or for more than 15 minutes within a 2-hour period. A manual restraint does not include physically prompting, escorting or guiding an individual to a support as specified in the individual's PSP." MR Bulletin 00-06-09: page 7: " Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per 55 PA Code 6500.172, 6400.202, 2380.161(d)." Further the proposed definition does not align with **6000.923** Incidents to be reported within 72 hours: "(a) (2) (i) "Restraints: Physical. A physical or manual restraint is a physical hands-on technique that lasts 30 seconds or more used to control acute, episodic behavior that restricts the movement or function of an individual or portion of an individual's body such as a basket hold ..." :	Would ask that the definitions that are currently being followed as set forth in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q replace those that are in the proposed regulations to maintain consistency of implementation for providers.
2390.174	Permitted interventions	Definitions are given within this section. Also many of these definitions differ from current definitions given in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q	Ask that all definitions be at the beginning of the chapter. Further ask that definitions remain as currently identified in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q

Citation	Caption	Discussion	Recommendation
2390.175	Access to or the use of individuals personal property	"(b) (2)Consent shall be obtained in the presence of the individual, a person designated by the individual and in the presence of and with the support of the support coordinator or targeted support manager" : We acknowledge that we need consent for incidences of restitution however the requirement of all the named parties to be in attendance when the consent is obtained will cause undue burden on providers as an actual meeting will need to be held to have all parties present.	Ask that this be reworded such that the individual in the presence of at least one other person by allowed for the obtainment of the consent
2390.176	Rights team:	(c) "Members of the rights team shall include the affected individual, persons designated by the individual, a family member or an advocate appointed by the designated managing entity if the individual is unable to speak for himself, the individual's support coordinator or targeted support manager, a representative from the designated managing entity and a facility representative.": Providers currently follow Chapter 6000 Subchapter Q: Incident Management. A Restrictive Procedure review team already is mandated and is comprised of various members review incidents and restraints. Membership of this the Rights Team in these regulations, to include the individual, persons designated by the individual or designated managing entity, the support coordinator or targeted support manager for EACH individual would be extremely difficult to implement as a provider serving a large number of individuals.	Recommend that the process established under Chapter 6000 Subchapter Q remain as the standard to be implemented..

Comments on Proposed Chapter 2390

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
2390.176	Rights team:	"(e) If a restraint was used, the individual's health care practitioner shall be consulted." : Worded in this manner does not allow for restraints that included in an approved intervention plan. If in a plan the health care practitioner may approve use and then would not need to be contacted everytime. It is not feasible for providers to contact health care practitioners every time a restraints used.	Ask that this be removed or reworded to allow for health care practitioner approval of restraint to be used as written within an intervention plan.
2390.191	Medication: Self-administration:	In review of the proposed regulations revisions to current regulation, it is felt that imposing all the identified within regulation will be difficult to maintain and align with the Department's medication administration training which is revised as appropriate based on medical profession changes.	Would ask that regulation mirror the Department's required training and not impose additional restrictions.
2390.191	Medication: Self-administration:	"(a) The facility shall provider an individual who has a prescribed medication with assistance, as needed, for the individual's self-administration of the medication. (b) Assistance in the self-administration of medication includes helping the individual to remember the schedule for taking the medication, offering the individual the medication at the prescribed times, opening a medication container and storing the medication in a secure place." and "(d) The PSP must identify if the individual is unable to self-administer medications. (e) To be considered able to self-administer medications, an individual shall do all of the following:..." : This is a big change from current requirements for self-administration. Assistance of any sort is currently not allowed, so opening this to allow for all this assistance removes some of the independence required for self-administration.	Big change for providers in now allowing for assistance to self-administer. Alignment with self-administration assessments and the Department Medication Training course needs to be maintained.

Citation	Caption	Discussion	Recommendation
2390.194	Labeling of medications:	(4)"The prescribed dosage and instructions for administration" (5) "The name and title of the prescriber" : These are new to regulation and out of the control of the provider as labeling comes from the pharmacy filling the prescription.	Would ask this be removed.
2390.195	Prescription medications:	(a)"A prescription medication shall be prescribed in writing by an authorized prescriber." (e) "Changes in medication may only be made in writing by the prescriber...? : Do these allow for e-scriptions?	Would ask for rewording for clarification to include e-scribing.
2390.196	Medication record:	Wording change to "Medication record" from "Medication Log". The following are all new to regulations as being required in the medication record. By adding all this required information all medications prescribed to an individual will cause a medication record to increase extensively in size. Time required of staff to document all this will be extensive and take time away from providing direct service to individuals.	Ask that current medication log requirements remain
		(2) "Name and title of the prescriber"	
		(3) "Drug allergies"	
		(5) "Strength of medication"	
		(6) "Dosage form"	
		(7) "Dose of medication"	
		(8) "Route of administration"	
		(9) "Frequency of administration"	
		(10) "Administration times"	
		(11) "Diagnosis or purpose for the medication, including pro re nata"	
		(13) "Name and initials of person administering the medication"	
		(14) "Duration of treatment, if applicable"	
		(15) "Special precautions, if applicable"	

Citation	Caption	Discussion	Recommendation
		(16) "Side effects of the medication, if applicable": Unclear if this is referencing inclusion of all potential side effects of a medication, or just those identified by the prescriber to the individual.	
2390.196	Medication record:	(c))"If an individual refuses to take a prescribed medication, the refusal shall be documented on the medication record. The refusal shall be reported to the prescriber within 24 hours, unless otherwise instructed by the prescriber. Subsequent refusals to take a prescribed medication shall be reported as required by the prescriber": Contact to the prescriber each time a refusal occurs will cause undue imposition on prescribers. For providers to ask each prescriber for specific instruction regarding notification instructions puts additional requirements and monitoring.	Ask that requirement of notification to the prescriber be removed or re-written such that it reads "As instructed by the prescriber, notification of refusal will be reported."
2390.197	Medication errors:	The 2390s do not identify as 6100.467 (b) identifies that medication errors are to be reported immediately to the prescriber. 2390.197 (b) has the only requirement of "Documentation of medication errors, follow-up action taken and the prescriber's response shall be kept in the individual's record." Lack of the requirements identified in 6100.467 will cause confusion for providers as to what is actually required.	Ask that regulations be consistent across chapters.

Comments on Proposed Chapter 6400 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
		Throughout the proposed chapter wording used is "The home..." For most of the items that this wording is now used, it is actually "The provider...." who fulfills these requirements not each home.	Ask that wording be revised to remove requirements from being identified for "The home...." to read "The provider...."
6400.18	Incident report and investigation	(a) "The provider shall report the following incidents, alleged incidents and suspected incidents through the Department's information management system within 24 hours of discovery by a staff person: (13) Use of a restraint" ; : Currently per 6000.823 Incidents to be reported within 72 hours, includes Medication Error and Restraints. Unclear as to why the state is changing to require these to be reported within 24 hours. This will be a hardship on providers to maintain this added reporting, especially as there are no exceptions. The current reporting system has these as being required within 72 hours not 24.	Ask that Restraints continue to be reported within 72 hours of discovery.
6400.18	Incident report and investigation:	6100.401 (16) "A medication administration error, including prescription and over the counter medication administration errors.": This is not included in 6400.18. Is this an oversight?	Ask for review and consistency across regulations. If medication error is to be added for reporting, would ask it be in the current 72 hour timeframe.
6400.18	Incident report and investigation:	"(a) The home shall report....."; (c) The home shall keep....." ; (f) The home shall initiate,..." ; (h) The home shall finalize...."; (i) The home shall provide the following information....". : These are overseen and completed by various persons within the provider's organization, not each separate home.	Ask that the wording be revised to "The provider will...."

Comments on Proposed Chapter 6400 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6400.18	Incident report and investigation:	"(g) A Department-certified incident investigator shall conduct the investigation of the incident listed in subsection (a)" : As written this implies that ALL incidents will require an investigation to be completed. Providers already have multiple staff trained as certified investigators, but to expand and require all incidents to be investigated, these trained investigators will not have time to fulfill their program job responsibilities as they will be conducting investigations. 6000.925 "Categories of incidents to be investigated" identified specific categories of incidents that did and did not require investigation.	Ask that the categories of incidents currently identified in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q requiring investigation be incorporated to the 6100s.
6400.32	Rights of the individual	"(r) "An individual has the right to lock the individual's bedroom door": This statement, without any exceptions is troublesome in relation to potential health and safety issues of individuals. Further concern arises in that 6100.443 also states the individual is to have key, access card, or keypad code to access the home. This is not included here, which we appreciate.	Would ask this be revised to allow for exceptions as identified within an individual's PSP, or remove altogether. Would ask that key, access card, or keypad code to access the home as stated in 6100.443 NOT be added here but be removed from the 6100s.
6400.32	Rights of the individual:	(s) "An individual has the right to access food at any time": This statement, without any exceptions being identified is troublesome in relation to health and safety issues of individuals.	Would ask this be revised to allow for exceptions as identified within an individual's PSP, or remove altogether.
6400.47	Annual training plan	"(a) The home shall design...." : This is something that the provider would design not each separate home.	Ask that the wording be revised to "The provider will...."

Citation	Caption	Discussion	Recommendation
6400.48	Orientation program	(a) "Prior to working alone with individuals, and within 30 days after hire the following shall complete an orientation program as described in subsection (b)" "(1) Management, program, administrative and fiscal staff persons" "(2) Dietary, housekeeping, maintenance and ancillary staff persons. (5) Paid and unpaid interns who will work alone with individuals (6) Consultants who will work alone with individuals.": The wording of "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual..." is questioned in relation to the inclusion of "administrative and fiscal staff persons"; "housekeeping, maintenance..staff persons" as these staff positions do not provider direct support or service to individuals. For interns and consultants, scheduling of the required training and payment for their hours will be extremely difficult for providers to achieve. Requiring them to complete the outlined orientation training will be difficult to schedule and costly to providers to pay for the training hours.	Remove these positions from the training requirements as they are not appropriate to fulfillment of their job responsibilities.
6400.49	Annual training	(b) The following staff persons shall complete 12 hours of training each year: (1) Management, program, administrative and fiscal staff persons. (2) Dietary, housekeeping, maintenance and ancillary staff persons. ": Requiring fiscal, dietary, housekeeping and maintenance persons to obtain 12 hours of annual training in the identified areas will be burdensome to providers and these training do not have a direct correlation to their job responsibilities.	Remove these positions from the training requirements as they are not appropriate to fulfillment of their job responsibilities.

Comments on Proposed Chapter 6400 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6400.161	Medication: Self-administration:	"(a)A home shall provide an individual who has a prescribed medication with assistance, as needed, for the individual's self-administration of the medication. (b) Assistance in the self-administration of medication includes helping the individual to remember the schedule for taking the medication, offering the individual the medication at the prescribed times, opening a medication container and storing the medication in a secure place." and "(d) The PSP must identify if the individual is unable to self-administer medications. (e) To be considered able to self-administer medications, an individual shall do all of the following:..." : This is a big change from current requirements for self-administration. Assistance of any sort is currently not allowed, so opening this to allow for all this assistance removes some of the independence required for self-administration.	Big change for providers in now allowing for assistance to self-administer. Alignment with self-administration assessments and the Department Medication Training course needs to be maintained.
6400.164	Labeling of medications:	(4)"The prescribed dosage and instructions for administration" (5) "The name and title of the prescriber" : These are new to regulation and out of the control of the provider as labeling comes from the pharmacy filling the prescription.	Would ask this be removed.
6400.165	Prescription medications:	(a)"A prescription medication shall be prescribed in writing by an authorized prescriber." (e) "Changes in medication may only be made in writing by the prescriber...? : Do these allow for e-scriptions?	Would ask for rewording for clarification to include e-scribing.

Citation	Caption	Discussion	Recommendation
6400.199	Medication record:	Wording change to "Medication record" from "Medication Log". The following are all new to regulations as being required in the medication record. By adding all this required information all medications prescribed to an individual will cause a medication record to increase extensively in size. Time required of staff to document all this will be extensive and take time away from providing direct service to individuals.	Ask that current medication log requirements remain
		(2) "Name and title of the prescriber"	
		(3) "Drug allergies"	
		(5) "Strength of medication"	
		(6) "Dosage form"	
		(7) "Dose of medication"	
		(8) "Route of administration"	
		(9) "Frequency of administration"	
		(10) "Administration times"	
		(11) "Diagnosis or purpose for the medication, including pro re nata"	
		(13) "Name and initials of person administering the medication"	
		(14) "Duration of treatment, if applicable"	
		(15) "Special precautions, if applicable"	
		(16) "Side effects of the medication, if applicable": Unclear if this is referencing inclusion of all potential side effects of a medication, or just those identified by the prescriber to the individual.	

Comments on Proposed Chapter 6400 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6400.199	Medication record:	(c))"If an individual refuses to take a prescribed medication, the refusal shall be documented on the medication record. The refusal shall be reported to the prescriber within 24 hours, unless otherwise instructed by the prescriber. Subsequent refusals to take a prescribed medication shall be reported as required by the prescriber": Contact to the prescriber each time a refusal occurs will cause undue imposition on prescribers. For providers to ask each prescriber for specific instruction regarding notification instructions puts additional requirements and monitoring.	Ask that requirement of notification to the prescriber be removed or re-written such that it reads "As instructed by the prescriber, notification of refusal will be reported."
6400.167	Medication errors:	The 6400s do not identify as 6100.467 (b) identifies that medication errors are to be reported immediately to the prescriber. 6400.167 (b) has the only requirement of "Documentation of medication errors, follow-up action taken and the prescriber's response shall be kept in the individual's record." Lack of the requirements identified in 6100.467 will cause confusion for providers as to what is actually required.	Ask that regulations be consistent across chapters.
6400.182	Development of the PSP	"(c) The support coordinator or targeted support manager <u>or program specialist</u> shall be responsible for the development of the PSP...": Wording varies on this to 6100.221 which states: " (c) The support coordinator, targeted support manager ...." The addition of "or the program specialist" in separate licensing chapters adds confusion as to who is to oversee the development of the PSP.	Would ask that wording be revised to exclude "program specialist" in the 6400 regulations to be consistent with the 6100s.
6400.191	Use of a positive intervention	Definitions are given for "Dangerous behavior" and "Positive intervention" within this section.	Ask that all definitions be at the beginning of the chapter.
6400.192	Positive intervention: PSP	This 6400 tag does not include " Communication needs" as does tag 6100.342	Ask that there be consistency across regulation chapters.

Citation	Caption	Discussion	Recommendation
6400.193	Prohibition of restraints	Definitions are given within this section.	Ask that all definitions be at the beginning of the chapter.
6400.193	Prohibition of restraints	In this tag definitions of various restraints are given, many of which are newly defined when compared to those currently being followed as per MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q. Of specific concern is the difference between **6400.193 (6)** "A manual restraint, defined as a hands-on physical method that restricts, immobilized or reduces an individual's ability to move his arms, legs, head or other body parts freely, on a nonemergency basis, or for more than 15 minutes within a 2-hour period. A manual restraint does not include physically prompting, escorting or guiding an individual to a support as specified in the individual's PSP." MR Bulletin 00-06-09: page 7: " Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per 55 PA Code 6500.172, 6400.202, 2380.161(d)." Further the proposed definition does not align with **6000.923** Incidents to be reported within 72 hours: "(a) (2) (i) "Restraints: Physical. A physical or manual restraint is a physical hands-on technique that lasts 30 seconds or more used to control acute, episodic behavior that restricts the movement or function of an individual or portion of an individual's body such as a basket hold ..." :	Would ask that the definitions that are currently being followed as set forth in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q replace those that are in the proposed regulations to maintain consistency of implementation for providers.
6400.194	Permitted interventions	Definitions are given within this section. Also many of these definitions differ from current definitions given in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q	Ask that all definitions be at the beginning of the chapter. Further ask that definitions remain as currently identified in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q

Comments on Proposed Chapter 6400 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6400.194	Permitted interventions	(h) "As used in this section , a "physical protective restraint" is a hands-on hold of an individual"	Move this definition to beginning of the chapter with other Definitions and incorporate earlier in this section such as in (b) so readers know what is being talked about.
6400.194	Permitted interventions	(f) "A physical protective restraint may not be used for more than 15 minutes within a 2-hour period" : Putting this time constraint on the used of a physical protective restraint for some individuals will not allow for their health and safety or that of others. Currently MR Bulletin 00-06-09 page 7 "Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per current 55 PA Code 6500.172; 6400.202; 2380.161(d). An individual is immediately released from physical restraint when they no longer present a danger to self or others."	Ask that the time constraint be revised to the current as mandated in MR Bulletin 00-06-09 and current licensing regulations to maintain the health and safety of all individuals.
6400.195	Access to or the use of individuals personal property	"(b) (2)Consent shall be obtained in the presence of the individual, a person designated by the individual and in the presence of and with the support of the support coordinator or targeted support manager" : We acknowledge that we need consent for incidences of restitution however the requirement of all the named parties to be in attendance when the consent is obtained will cause undue burden on providers as an actual meeting will need to be held to have all parties present.	Ask that this be reworded such that the individual in the presence of another person be allowed for the obtainment of the consent
6400.196	Rights team	"(a) The home shall have a rights team. The home may...." : This is not something that each separate home should be developing. The provider has a restrictive review team as required by Chapter 6000 Subchapter Q.	Revise this wording from "The home...." to "The provider.

Citation	Caption	Discussion	Recommendation
6400.196	Rights team	(c) "Members of the rights team shall include the affected individual, persons designated by the individual, a family member or an advocate appointed by the designated managing entity if the individual is unable to speak for himself, the individual's support coordinator or targeted support manager, a representative from the designated managing entity and a provider representative.": Providers currently follow Chapter 6000 Subchapter Q: Incident Management. A Restrictive Procedure review team already is mandated and is comprised of various members review incidents and restraints. Membership of this the Rights Team in these regulations, to include the individual, persons designated by the individual or designated managing entity, the support coordinator or targeted support manager for EACH individual would be extremely difficult to implement as a provider serving a large number of individuals.	Recommend that the process established under Chapter 6000 Subchapter Q remain as the standard to be implemented..

Comments on Proposed Chapter 6500 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6500.20	Incident report and investigation	(a) "The provider shall report the following incidents, alleged incidents and suspected incidents through the Department's information management system within 24 hours of discovery by a staff person: (13) Use of a restraint" ; : Currently per 6000.823 Incidents to be reported within 72 hours, includes Medication Error and Restraints. Unclear as to why the state is changing to require these to be reported within 24 hours. This will be a hardship on providers to maintain this added reporting, especially as there are no exceptions. The current reporting system has these as being required within 72 hours not 24.	Ask that Restraints continue to be reported within 72 hours of discovery.
6500.20	Incident report and investigation	"(c) The agency and the home shall keep documentation of the notification in subsection (b) " : It would be an imposition on the life sharer to maintain this information. It seems appropriate to have the provider maintain this documentation, not the home.	Remove "...and the home" from this tag.
6500.20	Incident report and investigation	"(e) The agency shall take immediate action to protect the health, safety, and well-being of the individual following the initial knowledge or notice of an incident alleged incident and suspected incident." : Question why here "The agency...." is identified and not the home, as these regulations are for the home.	Ask that wording here be reviewed and revision made as appropriate.
6500.20	Incident report and investigation:	6100.401 (16) "A medication administration error, including prescription and over the counter medication administration errors.": This is not included in 6500.20 Is this an oversight?	Ask for review and consistency across regulations. If medication error is to be added for reporting, would ask it be in the current 72 hour timeframe.

6500.20	Incident report and investigation:	"(g) A Department-certified incident investigator shall conduct the investigation of the incident listed in subsection (a)" : As written this implies that ALL incidents will require an investigation to be completed. Providers already have multiple staff trained as certified investigators, but to expand and require all incidents to be investigated, these trained investigators will not have time to fulfill their program job responsibilities as they will be conducting investigations. 6000.925 "Categories of incidents to be investigated" identified specific categories of incidents that did and did not require investigation.	Ask that the categories of incidents currently identified in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q requiring investigation be incorporated to the 6100s.
6500.20	Incident report and investigation:	"(f) The home shall initiate an investigation of an incident within 24 hours of discovery by a staff person." : Investigations are initiated by the provider not each separate home, as certified investigators are various staff persons within the provider agency.	Ask that this wording be revised to "The provider..." or "The agency...."
6500.32	Rights of the individual	"(g) An individual has the right to control the individual's own schedule": 6100.182 "(g) An individual has the right to control the individual's own schedule and activities."	Ask that consistency across regulations in identified rights.
6500.32	Rights of the individual	"(r) "An individual has the right to lock the individual's bedroom door": This statement, without any exceptions is troublesome in relation to potential health and safety issues of individuals. Further concern arises in that 6100.443 also states the individual is to have key, access card, or keypad code to access the home. This is not included here, which we appreciate. As a life sharing home is not the property of the provider agency, requiring a life sharer to put a lock on the door is inappropriate as within a family home bedroom doors do not generally lock with a key.	Would ask that this be removed from the 6500 regulations. If not removed, would ask this be revised to allow for exceptions as identified within an individual's PSP. Would ask that key, access card, or keypad code to access the home as stated in 6100.443 NOT be added here but be removed from the 6100s.
6500.32	Rights of the individual:	(s) "An individual has the right to access food at any time": This statement, without any exceptions being identified is troublesome in relation to health and safety issues of individuals.	Would ask this be revised to allow for exceptions as identified within an individual's PSP, or remove altogether.

6500.48	Annual training	"(a) The primary caregiver and the life sharing specialist shall complete 24 hours of training each year" : The addition of this requirement on a primary caregiver seems excessive. The areas identified of the required minimum of 8 hours seem appropriate, however as primary caregivers are not employees it would be extremely difficult to schedule and compensate them for 24 hours of training.	Recommend removal of the 24 hour requirement for the primary caregiver.
6500.134	Labeling of medications:	(4)"The prescribed dosage and instructions for administration" (5) "The name and title of the prescriber" : These are new to regulation and out of the control of the provider as labeling comes from the pharmacy filling the prescription.	Would ask this be removed.
6500.135	Prescription medications:	(a)"A prescription medication shall be prescribed in writing by an authorized prescriber." (e) "Changes in medication may only be made in writing by the prescriber...? : Do these allow for e-scriptions?	Would ask for rewording for clarification to include e-scribing.
		Wording change to "Medication record" from "Medication Log". The following are all new to regulations as being required in the medication record. By adding all this required information all medications prescribed to an individual will cause a medication record to increase extensively in size. Time required of staff to document all this will be extensive and take time away from providing direct service to individuals.	
		(2) "Name and title of the prescriber"	
		(3) "Drug allergies"	
		(5) "Strength of medication"	
		(6) "Dosage form"	
		(7) "Dose of medication"	
		(8) "Route of administration"	
		(9) "Frequency of administration"	
		(10) "Administration times"	
		(11) "Diagnosis or purpose for the medication, including pro re nata"	

6500.136	Medication record:	(13) "Name and initials of person administering the medication" (14) "Duration of treatment, if applicable" (15) "Special precautions, if applicable" (16) "Side effects of the medication, if applicable": Unclear if this is referencing inclusion of all potential side effects of a medication, or just those identified by the prescriber to the individual.	Ask that current medication log requirements remain
6500.136	Medication record:	(c))"If an individual refuses to take a prescribed medication, the refusal shall be documented on the medication record. The refusal shall be reported to the prescriber within 24 hours, unless otherwise instructed by the prescriber. Subsequent refusals to take a prescribed medication shall be reported as required by the prescriber": Contact to the prescriber each time a refusal occurs will cause undue imposition on prescribers. For providers to ask each prescriber for specific instruction regarding notification instructions puts additional requirements and monitoring.	Ask that requirement of notification to the prescriber be removed or re-written such that it reads "As instructed by the prescriber, notification of refusal will be reported."
6500.137	Medication errors:	The 6400s do not identify as 6100.467 (b) identifies that medication errors are to be reported immediately to the prescriber. 6400.167 (b) has the only requirement of "Documentation of medication errors, follow-up action taken and the prescriber's response shall be kept in the individual's record." Lack of the requirements identified in 6100.467 will cause confusion for providers as to what is actually required.	Ask that regulations be consistent across chapters.
6500.152	Development of the PSP	"(c) The support coordinator or targeted support manager or life sharing specialist shall be responsible for the development of the PSP...": Wording varies on this to 6100.221 which states: " (c) The support coordinator, targeted support manager ...." The addition of "or the life sharing specialist" in separate licensing chapters adds confusion as to who is to oversee the development of the PSP.	Would ask that wording be revised to exclude "life sharing specialist" in the 6500 regulations to be consistent with the 6100s.

6500.161	Positive Intervention: Use of a positive intervention	Definitions are given for "Dangerous behavior" and "Positive intervention" within this section.	Ask that all definitions be at the beginning of the chapter.
6500.162	Positive intervention: PSP	This 6400 tag does not include " Communication needs" as does tag 6100.342	Ask that there be consistency across regulation chapters.
6500.163	Prohibition of restraints	Definitions are given within this section.	Ask that all definitions be at the beginning of the chapter.
6500.163	Prohibition of restraints	In this tag definitions of various restraints are given, many of which are newly defined when compared to those currently being followed as per MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q. Of specific concern is the difference between **6500.163 (6)** "A manual restraint, defined as a hands-on physical method that restricts, immobilized or reduces an individual's ability to move his arms, legs, head or other body parts freely, on a nonemergency basis, or for more than 15 minutes within a 2-hour period. A manual restraint does not include physically prompting, escorting or guiding an individual to a support as specified in the individual's PSP." MR Bulletin 00-06-09: page 7: " Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per 55 PA Code 6500.172, 6400.202, 2380.161(d)." Further the proposed definition does not align with **6000.923** Incidents to be reported within 72 hours: "(a) (2) (i) "Restraints: Physical. A physical or manual restraint is a physical hands-on technique that lasts 30 seconds or more used to control acute, episodic behavior that restricts the movement or function of an individual or portion of an individual's body such as a basket hold ..." :	Would ask that the definitions that are currently being followed as set forth in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q replace those that are in the proposed regulations to maintain consistency of implementation for providers.
6500.164	Permitted interventions	Definitions are given within this section.	Ask that all definitions be at the beginning of the chapter.
6500.164	Permitted interventions	(h) "As used in this section , a "physical protective restraint" is a hands-on hold of an individual"	Move this definition to beginning of the chapter with other Definitions and incorporate earlier in this section such as in (b) so readers know what is being talked about.

6500.164	Permitted interventions	(f) "A physical protective restraint may not be used for more than 15 minutes within a 2-hour period" : Putting this time constraint on the used of a physical protective restraint for some individuals will not allow for their health and safety or that of others. Currently MR Bulletin 00-06-09 page 7 "Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per current 55 PA Code 6500.172; 6400.202; 2380.161(d). An individual is immediately released from physical restraint when they no longer present a danger to self or others."	Ask that the time constraint be revised to the current as mandated in MR Bulletin 00-06-09 and current licensing regulations to maintain the health and safety of all individuals.
6500.165	Access to or the use of individuals personal property	"(b) (2)Consent shall be obtained in the presence of the individual, a person designated by the individual and in the presence of and with the support of the support coordinator or targeted support manager" : We acknowledge that we need consent for incidences of restitution however the requirement of all the named parties to be in attendance when the consent is obtained will cause undue burden on providers as an actual meeting will need to be held to have all parties present.	Ask that this be reworded such that the individual in the presence of one other person be allowed for the obtainment of the consent
6500.166	Rights team	"(a) The home shall have a rights team. The home may...." : This is not something that each separate home should be developing. The provider has a restrictive review team as required by Chapter 6000 Subchapter Q.	Revise this wording from "The home...." to "The provider.

6500.166	Rights team	(c) "Members of the rights team shall include the affected individual, persons designated by the individual, a family member or an advocate appointed by the designated managing entity if the individual is unable to speak for himself, the individual's support coordinator or targeted support manager, a representative from the designated managing entity and a provider representative.": Providers currently follow Chapter 6000 Subchapter Q: Incident Management. A Restrictive Procedure review team already is mandated and is comprised of various members review incidents and restraints. Membership of this the Rights Team in these regulations, to include the individual, persons designated by the individual or designated managing entity, the support coordinator or targeted support manager for EACH individual would be extremely difficult to implement as a provider serving a large number of individuals.	Recommend that the process established under Chapter 6000 Subchapter Q remain as the standard to be implemented..

Comments on Proposed Chapter 6100 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6100.3	Definitions:	There are many new definitions that appear in the 6100s but do not appear in the separate licensing chapters	Would recommend that all definitions (applicable to separate chapters) be added to each chapter for ease of reference as working within a chapter. Further would ask that ALL definitions be moved to this section for consistency, such as definitions given in 6100.34; 6100.343 Positive intervention section there are definitions which do not appear in this section.
6100.3	Definitions:	Although there are many new definitions in this section, there remain to be definitions within later tags. Example: 6100.341 Use of a positive intervention: "Dangerous behavior- An action with a high likelihood of resulting in harm to the individual or others." Additional definitions are found in 6100.341 Use of a positive intervention; 6100.343 Prohibition of restraints; 6100.344 Permitted interventions.	Would ask that ALL definitions be moved to this section for a comprehensive compilation of terms.
6100.42	Monitoring Compliance:	(i)"The directed corrective action plan shall be completed by the provider at the provider's expense and not eligible for reimbursement from the Department":	This has the potential to be a great monetary burden on the provider, especially if the state mandates a corrective action that widely effects the provider. (Ex. Mandating training for all staff from an outside source: The cost of the trainer and the cost of paying all staff to attend the training)
6100.42	Monitoring Compliance:	(k) "The provider shall keep documentation relating to an audit, provider monitoring or other monitoring method, including supporting compliance documents."	Do not see an identification of how long these documents must be kept in this tag. The time periods identified in 6100.54 Recordkeeping (c) (1) "For at least 4 years from the Commonwealth's fiscal year-end or 4 years from the provider's fiscal year-end, whichever is later. (2) Until any audit or litigation is resolved" seem appropriate. Add a time frame here.

Comments on Proposed Chapter 6100 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6100.46	Protective services	"(b) If there is an incident of abuse, suspected abuse or alleged abuse of an individual involving a staff person, consultant, intern or volunteer, the staff person, consultant, intern or volunteer may not have direct contact with an individual until the abuse investigation is concluded and the investigating agency has confirmed that no abus occurred." : As worded this does not address those instances that the investigation results in the incident as "unfounded".	Ask that wording be revised to allow for instances that investigations find the allegation to be unfounded.
6100.50	Communication:	(b) "The individual shall be provided with the assistive technology necessary to effectively communicate."	It is felt this statement is appropriate, however, as written there is no identification of who would pay for the assistive technology. Also have concern as some individuals refuse to utilize assistive devices. This statement does not reference the individual's choice to use or not use assistive technology. Addition of exceptions and cost coverage is requested.
6100.52	Rights team:	(c) "Members of the rights team shall include the affected individual, persons designated by the individual, a family member or an advocate appointed by the designated managing entity if the individual is unable to speak for himself, the individual's support coordinator or targeted support manager, a representative from the designated managing entity and a provider representative.": Providers currently follow Chapter 6000 Subchapter Q: Incident Management. A Restrictive Procedure review team already is mandated and is comprised of various members review incidents and restraints. Membership of this the Rights Team in these regulations, to include the individual, persons designated by the individual or designated managing entity, the support coordinator or targeted support manager for EACH individual would be extremely difficult to implement as a provider serving a large number of individuals.	Recommend that the process established under Chapter 6000 Subchapter Q remain as the standard to be implemented..

Comments on Proposed Chapter 6100 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6100.50	Rights team:	(e) "If a restraint was used, the individual's health care practitioner shall be consulted": As written this does not exclude use of approved restraint within an individual's PSP. Furthermore, as staff are trained in use of restraints, unless an injury occurs contact of a health care practitioner serves no true purpose.	Ask that exceptions be included as contacting a health care practitioner every time a restraint is used will cause undue strain on both the health care practitioner and the provider.
6100.141	Annual training plan:	(a) "annual training plan based on the needs of the individuals as specified in the individual's PSPs, the provider's quality management plan, and other data and analysis indicating training needs"	For large providers, to say annual training is to address "... needs of the individuals as specified in the individual's PSPs.." sets unattainable expectations as each individual has their own needs and to include ALL needs in an annual training plan would be impossible and inappropriate. We would ask that this be reworded.
6100.141	Annual training plan:		"...the providers quality management plan..." Wording is not included in separate regulatory chapters (2380,2390,6400,6500) it is just in the 6100s. We would ask for consistency across all regulatory chapters.

Comments on Proposed Chapter 6100 Regulations
Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6100.142	Orientation program:	(a) "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual the following shall complete an orientation program as described in subsection (b)" "(1) Management, program, administrative and fiscal staff persons" "(2) Dietary, housekeeping, maintenance and ancillary staff persons. The wording of "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual..." is questioned in relation to the inclusion of "administrative and fiscal staff persons"; "housekeeping, maintenance..staff persons" as these staff positions do not provider direct support or service to individuals. For interns and consultants, scheduling of the required training and payment for their hours will be extremely difficult for providers to achieve. Requiring them to complete the outlined orientation training will be difficult to schedule and costly to providers to pay for the training hours.	Remove positions of fiscal, dietary, housekeeping, and maintenance from the training requirements as they are not appropriate to fulfillment of their job responsibilities.
6100.142	Orientation program:	(a) "Prior to working alone with individuals, and within 30 days after hire or starting to provide support to an individual the following shall complete an orientation program as described in subsection (b)(7) Paid and unpaid interns who will work alone with individuals (8) Consultants who will work alone with individuals.": As these persons are not employees and may only provide limited services to a provider/individuals, scheduling and paying them to attend all the proposed annual trainings will be a burden on providers. Providers may offer appropriate training to these persons prior to their work with individuals.	Remove the number of hours of required training for these persons.

Citation	Caption	Discussion	Recommendation
6100.142	Orientation program:	(a) (5) "Life sharers": Terminology in the 6500.48 is "The primary caregiver...."	With the potential for a wider interpretation of "life sharers" here we would ask that you utilize consistent terminology of "primary caregiver" .
6100.143	Annual training:	"(b) The following staff persons and others shall complete 12 hours of training each year. (1) Management, program, administrative, fiscal, dietary, housekeeping, maintenance, and ancillary staff persons. (2) Consultants who provide reimbursed support to an individual and who work alone with individuals (4) Paid and unpaid interns who provide reimbursed supports to an individual and who work alone with individuals.": Concern of the appropriateness of this training for administrative, fiscal, housekeeping, maintenance staff persons. Also for the scheduling and payment for hours to consultants and interns for their attendance at the proposed trainings.	Ask that these requirements be removed for these positions.
6100.143	Annual training:	2380.39; 2390.42; 6400.49 (b) (3) Consultants who work alone with individuals. (5) Paid and unpaid interns who work alone with individuals"	Wording varies in this from 6100.143. We would ask that wording be consistent across all regulatory chapters.
6100.142	Orientation program:	(a) (4) "Household members who will provide reimbursed supports to the individual"	For AWC's this will be very burdensome and difficult to accomplish. Ask that AWC's be removed from being required to comply with the training requirements here.
6100.143	Annual training:	(a) (1) "Direct support staff persons, including <u>household members and life sharers</u> who provide reimbursed support to the individual.". 6500.48 reads: (a) The <u>primary caregiver</u> and the life sharing specialist shall....": Variations of wording leave interpretation unclear.	Ask that wording be consistent across all chapters of regulations. AWC's should be removed from this requirement.

Citation	Caption	Discussion	Recommendation
6100.182	Rights of the individual:	(g) "An individual has the right to control the individual's schedule and activities.": This is not found in the 2380s or 2390s. 6400.32 and 6500.32 Rights of the individual (g) reads "An individual has the right to control the individual's own schedule". Wording differs as in the 6400s and 6500s "activities" is not included.	Ask that wording and expectations be consistent across all chapters.
6100.182	Rights of the individual:	(j) An individual has the right to choose a willing and qualified provider (k) An individual has the right to choose where, when and how to receive needed supports." "(m) An individual has the right to assistive devices and support to enable communication at all times": (j) , (k) and (m) are not included in any separate regulation chapters. Would ask why these are not included in separate chapters.	Ask that there be consistency.
6100.183	Additional rights of the individual in a residential facility:	(g) "An individual has the right to lock the individual's bedroom door": This statement, without any exceptions is troublesome in relation to potential health and safety issues of individuals.	Would ask this be revised to allow for exceptions as identified within an individual's PSP, by the health care provider, or be removed altogether. Further ask that revision to 6400.32 and 6500.32 also be made to maintain consistency.
6100.183	Rights of the individual:	(h) "An individual has the right to access food at any time": This statement, without any exceptions being identified is troublesome in relation to health and safety issues of individuals.	Would ask this be revised to allow for exceptions as identified within an individual's PSP, or remove altogether. Further ask that revision to 6400.32 and 6500.32 also be made to maintain consistency.
6100.184	Negotiation of choices:	(a) "An individual's rights shall be exercised so that another individual's rights are not violated" and (b)"Choices shall be negotiated by the affected individuals in accordance with the provider's procedures for the individuals to resolve differences and make choices.": This section does not appear in the 2380s or 2390s.	Would ask for consistency across chapters.

Comments on Proposed Chapter 6100 Regulations
Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6100.221	Development of the PSP:	(c)"The support coordinator or targeted support manager shall be responsible for the development of the PSP...": Wording varies on this in separate regulation chapters: 2380.182; 2390.152; 6400.182; 6500.152 (c) "The support coordinator, targeted support manager or program (life sharing) specialist shall...." The addition of "or the program specialist" in separate licensing chapters adds confusion as to who is to oversee the development of the PSP.	Would ask that wording be revised to exclude "program (life sharing) specialist" in the program regulations to be consistent.
6100.262	Employment:	(a) "The individual shall have active and ongoing opportunities and the supports necessary to seek and retain employment and work in competitive, integrated settings": As written (a) does not allow for individual choose as not all individuals want to be employed or work in competitive integrated settings. Furthermore, wording of (a) seems to contradict (c) "At the annual PSP revision, the individual shall be offered appropriate opportunities related to the individual's skills and interests, and encouraged to seek competitive, integrated employment." This tag section is not seen in the 2380s or 2390s.	Recommend rewording to allow for individual choice and consistency across regulations by inclusion in 2380s and 2390s..
6100.304 6100.306	Written notice: Transition planning	6100.304(a) "If the individual chooses another provider, the PSP team shall provide written notice to the following....." 6100.306 "The support coordinator or targeted support manager shall coordinate the transition planning activities including scheduling and participating in all transition planning meetings during the transition period." : Not sure why in 6100.304 the PSP team is identified as sending the notice of the desire to transfer. In reading 6100.306 it would seem this would come from the support coordinator or targeted support manager.	Would ask that 6100.304 Written notice be revised to come from the support coordinator or targeted support manager for consistency.
6100.342	Positive Intervention: PSP:	(6) "Communication needs" : This does not appear in the separate chapter sections of 2380.152; 2390.172; 6400.192; and 6500.162 do not include this item.	Ask that all chapters contain consistent items and language to avoid confusion.

Comments on Proposed Chapter 6100 Regulations
Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6100.343	Prohibition of restraints	In this tag definitions of various restraints are given, many of which are newly defined when compared to those currently being followed as per MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q. Of specific concern is the difference between 6100.343 (6) "A manual restraint, defined as a hands-on physical method that restricts, immobilized or reduces an individual's ability to move his arms, legs, head or other body parts freely, on a nonemergency basis, or for more than 15 minutes within a 2-hour period. A manual restraint does not include physically prompting, escorting or guiding an individual to a support as specified in the individual's PSP." MR Bulletin 00-06-09: page 7: " Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per 55 PA Code 6500.172, 6400.202, 2380.161(d)." Further the proposed definition does not align with 6000.923 Incidents to be reported within 72 hours: "(a) (2) (i) "Restraints: Physical. A physical or manual restraint is a physical hands-on technique that lasts 30 seconds or more used to control acute, episodic behavior that restricts the movement or function of an individual or portion of an individual's body such as a basket hold ..." :	Would ask that the definitions that are currently being followed as set forth in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q replace those that are in the proposed regulations to maintain consistency of implementation for providers.
6100.343	Prohibition of restraints	6100.343(1) "Seclusion, defined as involuntary confinement of an individual in a room or area from which the individual is physically prevented or verbally directed from leaving" MR Bulletin 00-06-09 page 6 :"Seclusion is not used. Seclusion is defined as placing an individual in a locked room. A locked room includes a room with any type of engaged locking device,, such as a key lock, spring lock bolt lock, foot pressure lock or physically holding the door shut."	
6100.344	Permitted interventions	(h) "As used in this section , a "physical protective restraint" is a hands-on hold of an individual"	Move this definition to 6100.3 and incorporate earlier in this section such as in (b) so readers know what is being talked about.

Comments on Proposed Chapter 6100 Regulations

Submitted by Pamela Johns, Policy Compliance Project Specialist, Barber National Institute, Erie, PA

Citation	Caption	Discussion	Recommendation
6100.344	Permitted interventions	(f) "A physical protective restraint may not be used for more than 15 minutes within a 2-hour period" : Putting this time constraint on the used of a physical protective restraint for some individuals will not allow for their health and safety or that of others. MR Bulletin 00-06-09 page 7 "Manual (physical) restraint does not exceed 30 minutes within a two-hour time period, per current 55 PA Code 6500.172; 6400.202; 2380.161(d). An individual is immediately released from physical restraint when they no longer present a danger to self or others."	Ask that the time constraint be revised to the current as mandated in MR Bulletin 00-06-09 and current licensing regulations to maintain the health and safety of all individuals.
6100.401	Incident Management: Types of incidents and timeframes for reporting	(a) "The provider shall report the following incidents, alleged incidents and suspected incidents through the Department's information management system within 24 hours of discovery by a staff person: (13) Use of a restraint" ; (16) "A medication administration error, including prescription and over the counter medication administration errors.": Currently per 6000.823 Incidents to be reported within 72 hours, includes Medication Error and Restraints. Unclear as to why the state is changing to require these to be reported within 24 hours. This will be a hardship on providers to maintain this added reporting, especially as there are no exceptions. The current reporting system has these as being required within 72 hours not 24.	Ask that Medication Error and Restraints continue to be reported within 72 hours of discovery.

Citation	Caption	Discussion	Recommendation
6100.402	Incident investigation	"(b) "The provider shall initiate an investigation of an incident within 24 hours of discovery by a staff person. (c) A Department-certified incident investigator whall conduct hte investigation of the incident listed in 6100.401 (a) (relating to types of incidents and timelines for reporting)." As written this implies that ALL incidents will require an investigation to be completed. Providers already have multiple staff trained as certified investigators, but to expand and require all incidents to be investigated, these trained investigators will not have time to fulfill their program job responsibilities as they will be conducting investigations. 6000.925 "Categories of incidents to be investigated" identified specific categories of incidents that did and did not require investigation.	Ask that the categories of incidents currently identified in MR Bulletin 00-06-09 and Chapter 6000 Subchapter Q requiring investigation be incorporated to the 6100s.
6100.443	Access to the bedroom and the home:	(a)"In a residential facility, an individual shall have a lock with a key, access card, keypad code or other entry mechanism to unlock and lock the individual's bedroom door <u>and the entrance of the home."</u> This item is not included in the proposed program regulations 640032 (r) ; 6500.32(r) Concern is raised for individuals to have a key to a home. For providers to change external locks on homes and give all individuals residing in the home a key or other method of access is not considered in the best interest for individuals safety. Loss of keys or giving them to inappropriate persons may occur and the safety of all individuals who reside there would be endangered. Further, locks on bedroom doors may not be appropriate for all individuals in relation to their health and safety. The number of keys that would be required would be at issue, as well as safety concerns. For life sharing families, it would pose an additional safety concern for their family.	Would ask that this be removed from the 6100s as it is not part of the 6400s or 6500s. If not removed would ask that allowance for exceptions as identified within the PSP or by health care providers be included.

Citation	Caption	Discussion	Recommendation
6100.443	Access to the bedroom and the home:	(f) "Access to an individual's bedroom shall be provided only in a life-safety emergency or with the express permission of the individual for each incident of access." : This regulation is excessive and does not take into account individuals who are not able to comprehend requests for access, or who have health and safety conditions that require monitoring both during personal care activities and when sleeping. There is also concern if individuals share a bedroom and they both do not give permission to enter.	Would ask that this be removed for the regulations to allow providers to continue to provide needed supports to individuals and the homes.
6100.446	Facility characteristics relating to size of facility:	(c) "A day facility that serves primarily persons with a disability, which is newly-funded in accordance...including an adult training facility licensed in accordance with Chapter 2380....and a vocational facility licensed in accordance with Chapter 2390...may not exceed a program capacity of 15 at any one time." : The limitation "program capacity of 15 at any one time" will prove difficult for providers to maintain. Providers will be forced to have more program sites, more vehicles to provide for outings and drop off and pick up by residential providers will prove to be an extreme challenge in scheduling. We understand the desire to integrate individuals into the community, however this limited number of persons will cause hardship for providers.	Would ask that the limit of 15 be removed or increased.
6100.447	Facility characteristics relation to location of facility:	(a) "A residential or day facility, which is newly-funded in accordance with this chapter on or after.....may not be located adjacent or in close proximity to the following: " : Question what will be considered "close proximity". It is understood that integration into the community is the goal, and establishment of campuses is discouraged, however to not be able to utilize buildings that may be located near all the identified facilities in (1-5) may cause difficult for providers to find appropriate sites.	Ask that this be removed or revised for more clarity.

Comments on Proposed Chapter 6100 Regulations
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Citation	Caption	Discussion	Recommendation
6100.447	Facility characteristics relation to location of facility:	"(1) Another human service residential facility": Question how providers are to know if there is a residential facility, i.e. home, that another provider owns? Not understanding the reasoning for this. Though it is understood that campuses are not to be created of facilities, it is unclear how and why 2 homes may not be in close proximity to each other, especially if operated by different providers.	Remove this.
6100.447	Facility characteristics relation to location of facility:	"(2) Another human service day facility serving primarily persons with a disability.": Question if this is referencing any disability, physical, emotional, intellectual....?	Remove this.
6100.447	Facility characteristics relation to location of facility:	"(3) A hospital": Strongly question why a facility may not be in "close proximity" to a hospital?	Remove this.
6100.447	Facility characteristics relation to location of facility:	"(4) A nursing facility": Strongly question why a facility may not be in "close proximity" to a nursing facility?	Remove this.
6100.447	Facility characteristics relation to location of facility:	"(5) A health or human service public or private institution." Unclear what all is implied here and do not understand why a facility may not be "in close proximity" ?	Remove this.
6100.461-469	Medication Administration:	In review of the proposed regulations revisions to current regulation, it is felt that imposing all the identified within regulation will be difficult to maintain and align with the Department's medication administration training which is revised as appropriate based on medical profession changes.	Would ask that regulation mirror the Department's required training and not impose additional restrictions.

Citation	Caption	Discussion	Recommendation
6100.461	Self-administration of medications:	(c) "The provider shall provide or arrange for assistive technology to support the individual's self-administration of medications"; (e) (3) "Know when the medication is to be taken. This knowledge may include reminders of the schedule and offering the medication at the prescribed times as specified in subsection (b) ". Current regulation 6400.169 and self-administration evaluation does not currently allow for any assistance or reminders. How will this align with training if regulation wording remains as written.	Would ask that this align with Department trainings.
6100.464	Labeling of medications:	(4)"The prescribed dosage and instructions for administration" (5) "The name and title of the prescriber" : These are new to regulation and out of the control of the provider as labeling comes from the pharmacy filling the prescription.	Would ask this be removed.
6100.465	Prescription medications:	(a)"A prescription medication shall be prescribed in writing by an authorized prescriber." (e) "Changes in medication may only be made in writing by the prescriber...? : Do these allow for e-scriptions?	Would ask for rewording for clarification to include e-scribing.
6100.466	Medication records:	Wording change to "Medication record" from "Medication Log". The following are all new to regulations as being required in the medication record. By adding all this required information all medications prescribed to an individual will cause a medication record to increase extensively in size. Time required of staff to document all this will be extensive and take time away from providing direct service to individuals.	Ask that current medication log requirements remain
		(2) "Name and title of the prescriber"	
		(3) "Drug allergies"	
		(5) "Strength of medication"	
		(6) "Dosage form"	
		(7) "Dose of medication"	
		(8) "Route of administration"	

Citation	Caption	Discussion	Recommendation
		(9) "Frequency of administration"	
		(10) "Administration times"	
		(11) "Diagnosis or purpose for the medication, including pro re nata"	
		(13) "Name and initials of person administering the medication"	
		(14) "Duration of treatment, if applicable"	
		(15) "Special precautions, if applicable"	
		(16) "Side effects of the medication, if applicable": Unclear if this is referencing inclusion of all potential side effects of a medication, or just those identified by the prescriber to the individual.	
6100.466	Medication records:	(c))"If an individual refuses to take a prescribed medication, the refusal shall be documented on the medication record. The refusal shall be reported to the prescriber within 24 hours, unless otherwise instructed by the prescriber. Subsequent refusals to take a prescribed medication shall be reported as required by the prescriber": Contact to the prescriber each time a refusal occurs will cause undue imposition on prescribers. For providers to ask each prescriber for specific instruction regarding notification instructions puts additional requirements and monitoring.	Ask that requirement of notification to the prescriber be removed or re-written such that it reads "As instructed by the prescriber, notification of refusal will be reported."

Citation	Caption	Discussion	Recommendation
6100.467	Medication errors:	(b) "A medication error shall be immediately reported as an incident as specified in 6100.401 (relating to types of incidents and timelines for reporting) and to the prescriber.": As previously commented we would ask that reporting of a medication error by returned to the current 72 hour timeframe. Further, for a provider to "immediately" report to the prescriber is not a reasonable requirement as many medications are administered at bedtime and prescribers are not available. This requirement also does not allow for exclusion per instruction from the prescriber as is given in 6100.466 for refusals. This requirement does not appear in separate chapter proposed regulations which will cause provider confusion as to what is required.	Ask that Medication Errors be maintained to be reported within 72 hours and reporting to prescriber be reworded to allow for prescriber exclusionary instruction.
6100.467	Medication errors:	(c) "Documentation of medication errors and the prescriber's response shall be kept in the individual's record": As proposed regulations require incident reporting of medication errors and such would be recorded in the medication record, it seems excessive to require additional documentation in individual records, other than inclusion of the incident report in the individual's record.	Ask that clarification be made that this documentation in the individual's record may be the incident report.