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#14-540

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**Kroh, Karen**

**From:** Mochon, Julie  
**Sent:** Tuesday, December 20, 2016 8:52 AM  
**To:** Kroh, Karen  
**Subject:** FW: Comments on Regulation No. 14-540  
**Attachments:** Comments on Regulation No. 14-540.pdf



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**From:** Bittner, Michele [mailto:[MBittner@clelianheights.org](mailto:MBittner@clelianheights.org)]  
**Sent:** Tuesday, December 20, 2016 8:42 AM  
**To:** Mochon, Julie  
**Subject:** Comments on Regulation No. 14-540

Good morning Julie,

Attached are my comments to the Proposed Regulation No. 14-540. Thank you,

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DEC 21 2016

# Comments on Proposed Rulemaking

Submitted by: Michele Bittner

Regulations in these chapters should be focused on the health and safety of the individuals served under these regulations. As written, information pertaining to certain topics are fragmented across the regulations, are not clear in their intentions, and are at times contradictory. Furthermore, the notes to the regulations mention that provider costs will fluctuate based on the new regulations, but implies minimum effect on costs. However, the proposed regulations create many increased responsibilities to providers, including training requirements, new "Rights Teams," and increased community employment regulations. Such requirements will have more than a minimum financial effect on providers and ultimately the Department.

## Chapter 6100 – General Provisions

Citation: **6100.1. Purpose (a)**

**Comments:** Language must be consistent with the CMS Community Rule for HCBS. CMS uses the term "services," which indicated a contractual agreement for payment and should be used in place of the proposed regulations term of "supports." The term "services" should be used in place of "supports" throughout this chapter.

Citation: **6100.42. Monitoring compliance**

**Recommendation:** Review of provider performance is customary, but also should require adherence by oversight entities to their duty to work in cooperation with providers. The tone and text in this section and elsewhere evinces a perspective that tends to focus on imposition of penalties as opposed to developing and implementing appropriate remedial actions when necessary.

When the Department designates monitoring to be done by a designated managing entity, all entities need to be consistent in their application and interpretation of the regulations. In current practice, different county AE's require different applications of regulations on providers during monitoring compliance. This adds to overhead, documentation and administrative costs that could be better served when focused on the quality of services to individuals.

Citation: **6100.43. Regulatory waiver**

**Recommendation:** The term "regulatory exception" is more appropriate than the term "regulatory waiver" in this context. In order to avoid instances of Department non-response, either a deadline for Department response or automatic approval after

a certain time period should be written into regulation. If the Department disapproves of the exception request, it must provide written explanation for the determination.

**Citation:** 6100.52. Rights team

**Recommendation:** While enhancing and expanding the rights of individuals is essential, this section appears not to accomplish this and only serves to add an unnecessary layer to the operation of providers and the responsibilities of families. Where the Department stated an intended goal to streamline processes and eliminate duplication, this accomplishes neither. In addition, it does not appear that any gaps in the current system exist that the addition of this new and additional expectation will fill.

The concept of evaluating the potential and actual violation of rights is absolutely a necessity, and one that is already appropriately covered in the Incident Management process which includes a thorough investigation by an investigator who was been certified in the Department-approved training. As part of the already well-established and robust Incident Management system, all allegations of rights violations must be investigated. If a violation of rights is confirmed, the process already has established corrective action expectations. The proposed regulatory changes in this chapter propose to enhance those expectations, and role of the PSP team as necessary, even further. The additional administrative expectation and associated costs associated with this section are unnecessary, inefficient and uneconomical.

According to the regulations, the “rights team” is to meet every three months, regardless of whether any actual rights violations occurred. This simply adds an expectation that it occurs every three months, adding unnecessary cost to the system and an additional administrative task. It is also unclear in wording who will need to meet as a rights team – whether the team is a standing organizational team or varied by individuals served.

A second stated purpose of the “rights team” is the review of any and all uses of restraint through the full convening of the rights team, including the use of techniques which are used for emergency scenarios in dangerous situations, and even part of a PSP.

In associated licensing regulations, a long-standing and well-established process exists for the oversight and appropriate management for the use of any restrictive procedures, including restraint. The regulations have already established the “Restrictive Procedures Committee” and restrictive procedures process which is tasked with the same basic functions of the newly created team. By replacing a currently existing and appropriately operating expectation, unnecessary costs are added to the system. It is entirely unclear why the creation of a new “rights team” is necessary or adds any value to the actual protection of individuals’ rights, but rather only would add cost and administrative burden.

**Also applies to 2380.156, 2390.176**

**Citation:** 6100.86. Delivery of HCBS

**Recommendation:** Statement (c) should read:

*A provider shall only be reimbursed for the HCBS to an individual who is authorized to receive that HCBS.*

As this regulatory chapter is intended to oversee all services that are reimbursed through the Department, it has no authority to determine what services a provider is able to deliver if the provider is not seeking reimbursement for these services.

**Citation:** 6100.141. Annual training plan

**Recommendation:** This section should be combined with section 6100.143 for clarity on training requirements.

**Citation:** 6100.143. Annual training

**Recommendation:** This section should be combined with section 6100.141 for clarity on training requirements. Annual training should not be required for all staff, specifically those that do not interact with individuals. After an initial training on person-center practices, individual rights, recognizing and reporting abuse, and others as deemed necessary, annual trainings would become an unnecessary cost. Retraining for these individuals might be more appropriate on a 5 year renewal basis.

**Also applies to 2380.39, 2390.49**

**Citation:** 6100.182. Rights of the individual

**Recommendation:** Statement (e) should be revised to state:

*An individual has the right to make informed choices and accept personal risks that do not pose a threat to the individual's and/or another person's health, safety or well-being.*

Each individual served does not exist in a vacuum. Regulations need to recognize the need to protect the rights of all individuals served under these regulations as a whole as well as on an individual basis.

**Also applies to 2380.21, 2390.21**

**Citation: 6100.221. Development of the PSP**

**Recommendation:** This section references a PSP as well as a service implementation plan. Language needs to be consistent to reflect one PSP that is used to authorize services eligible for reimbursement.

**Also applies to 2380.182, 2390.152**

**Citation: 6100.226. Documentation of support delivery**

**Recommendation:** The phrase “support delivery” should be replaced with “service delivery” to reflect documentation of reimbursable services, which are not to be confused with the general support of an individual or natural supports.

**Citation: 6100.261. Access to the community**

**Recommendation:** While each individual must have access to the broader community, this responsibility lies with the Department and not solely with the provider who provides specific services authorized by the Department. The Department must be a driving force and provide the financial and policy support to ensure compliance with the Community Rule.

Different providers may be authorized in an individual’s services to provide different types of services to the individual. Some of these services will be more community driven than others. It is important for an individual’s access to the community to be considered as a whole and in regard to what the individual desires. This should include both natural supports and reimbursable services provided by PSP approved providers in order to best reflect the Department’s implementation of Everyday Lives.

**Citation: 6100.262. Employment**

**Recommendation:** Language in statement (d) should be revised to include:

*The Department and Supports Coordinators or Targeted Supports Coordinators will ensure individuals have information and education about OVR services, and provide opportunities and the services necessary to seek and retain employment as desired and work in competitive, integrated settings as applicable.*

*Eligible individuals will be offered appropriate opportunities related to the individual's skills and interests, and encouraged to seek competitive, integrated employment, at each annual PSP review.*

It is extremely important that the regulations reflect the language and ideals of Everyday Lives. Specifically, with regard to Freedom, Control and Choice. Once opportunities are known, each individual should have the freedom to balance health, safety, and risk according to his/her wants and needs. The Department, Providers, and family members should respect decisions made by the individual, even if they are not the decisions that would have been made for the individual by others, provided that health and safety is maintained. These choices include services provided in settings with the individual's peers who may also be receiving services for those with intellectual disabilities.

**Citation:** 6100.304. Written notice

**Recommendation:** Providers and individuals served should both require 30 days advance notice before transition. However, the transition may be sooner if agreed upon by both parties.

**Citation:** 6100.305. Continuation of support

**Recommendation:** This section needs language to clarify what recourse/options providers have in the scenario where another provider isn't being found willing and able to provide services to the individual.

**Citation:** 6100.306. Transition planning

**Recommendation:** This section can be easily moved under section 6100.302 and will fit there better than as a standalone section. This will allow for a more clarified reading of the regulation.

**Citation:** 6100.307. Transfer of records

**Recommendation:** This section can be easily moved under section 6100.302 and will fit there better than as a standalone section. This will allow for a more clarified reading of the regulation.

**Citation:** **6100.342. PSP**

**Recommendation:** This section should be included along with other PSP information in section 6100.223

**Citation:** **6100.343. Prohibition of restraints**

**Recommendation:** Change title to “Prohibition of certain types of restraints,” as it more accurately describes the content.

**Also applies to 2380.153, 2390.173**

**Citation:** **6100.402. Incident investigation**

**Recommendation:** This title should include “Incident Response and Investigations.” Appropriate responses to an incident might not warrant an investigation. Therefore, not all types of incidents should require investigation. Final incident reports should only include a corrective action plan if it is applicable to the situation.

**Also applies to 2380.17, 2390.18**

**Citation:** **6100.403. Individual needs**

**Recommendation:** This section should be combined with 6100.405 in order for clarity in application and read as “6100.403 Incident Analysis.”

**Citation:** **6100.405. Incident analysis**

**Recommendation:** This section should be included in 6100.403 as “Incident Analysis,” as this information should read before information on the final incident report.

Not all incidents are avoidable, so the requirement of a corrective action plan should not be required for all incidents and should instead be required as appropriate. All incidents should be reviewed quarterly for trends. However, if this section uses the term “trend analysis,” such a term needs to be defined as to what is expected out of such analysis.

**Citation:**      **6100.441. Request for and approval of changes**

**Recommendation:** There are many situations within which individuals would benefit from rapid placement. These situations include natural disasters, program closures, and removal from abuse. It is important that this chapter allow the Department to develop an expedited capacity change process to accommodate individual’s needs in their everyday lives.

**Citation:**      **6100.442. Physical accessibility**

**Recommendation:** This item can create remarkable costs. The Department needs to develop capacity to compensate providers for these costs in their rate-setting process. Such reimbursement should be referenced in regulation to avoid becoming an unfunded mandate.

**Citation:**      **6100.444. Lease or ownership**

**Recommendation:** It is necessary under the Community Rule that individuals have a legally enforceable document that offers the same responsibilities and protections from eviction as our prevailing law. To that point, 6100.444(a) is clear and direct. 6100.444(b) while describing reasonable limits, inadvertently refers to providers as “landlords” and to individuals as “tenants” and their units as “leased space”. The rights conferred under the rule and as cited in 6100.444(a) do not make providers landlords. Having the same protections as provided by law does not make individuals tenants nor their spaces “leased”. This language distinction is important in that we need to preserve the American Disability Act’s protection of community residences as homes rather than businesses which can be excluded from residentially zoned areas. This distinction will also be crucial if/when the state

develops guiding language or uniform formatting for the residency or room and board agreements in the future.

**Citation:** 6100.445. Integration

**Recommendation:** Language should read “A setting in which a service is provided shall be integrated and accessible in and to the community...”

Such language better represents the CMS Settings Rule for community integration that states that individuals served must have support to fully access the greater community.

**Citation:** 6100.446. Facility characteristics relating to size of facility

**Recommendation:** Community Rule does not specify an absolute cap on program size. Smaller size programs require additional staffing levels, additional facility costs, and contribute to the workforce shortage. (DHS itself has recently approved larger census programs for individuals with medical needs.) The CMS response 441.530(a)(2)(V): “We do not believe there is a maximum number that we could determine with certainty that the setting would meet the requirements of HCB setting. The focus should be on the experience of the individual in the setting.”

**Comments on Section: Medication Administration**

There are two extremely important issues concerning the proposed new regulations pertaining to medication administration. These need to be addressed to prevent unintended negative consequences.

1. Codifying content that requires modifications over time into regulations will lock a crucial component of service provision into temporal practices which will become obsolete as new information, prevailing practices and technology emerge.  
Duplicating content which is as detail-specific as the proposed five-and-a-half pages of regulation across 5 sets of regulations when the state already has an externally - accepted training module invites discrepancy between the regulations and the training manual and prohibits the training module from staying current as new information, prevailing practices and technology emerge.
2. Requiring 6500 LifeSharing providers to complete and adhere to ODP’s Medication Administration Module is a new and counterproductive requirement which is in direct contract to Everyday Lives principals and the Department’s stated intent to develop more integrated and natural life opportunities for individuals.

As a ready example of the problem with codifying material which requires change over time, an area has been identified in which the proposed regulations are at odds with prevailing practices as detailed by Title 49 of the State Nursing Board. 49 PA. CODE CH. 21 explicitly provides for Licensed Practical Nurses to accept oral orders for administering medication. The proposed 6100.465 provision only allows this practice for Registered Nurses. This discrepancy is instructive both to the specific issue regarding LPN's and to the process issue of codifying Nursing Practices content which changes from time to time according to authorities outside of the Department. It is noted that the provider system needs LPN's to be able to do all that state law provides for them to do. In the second case, we need regulations which do not lock providers to standards which may soon become obsolete due to new and emerging best practices and advances.

A second example of the problem with trying to maintain this content in multiple places is that there are already discrepancies between the proposed 6100's and the Department's Approved Medication Administration Training. The training's required checklist for medication self-administration has discrepancies with the proposed regulation. There is also a notable practice discrepancy regarding pre-pouring of medications. We should avoid such confusion by maintaining this content in just one place, namely the Medication Administration Training module and not regulations.

**Citation:**      **6100.461. Self-administration**

**Recommendation:** The PSP team should be responsible for the facilitating the use of assistive technology to support an individual's self-administration of medications as appropriate, not individual providers.

**Also applies to 2380.121, 2390.191**

**Citation:**      **6100.462. Medication administration**

**Recommendation:** There was an inadvertent problem created by the inclusion of standardized medications content across these four program areas, which would include the 6500 regulations. If the 6500 LifeSharing programs are included in this requirement, significant unintended consequence are likely to severely impact the viability and expansion of this program; one which the Department has repeatedly stated they desire to expand. A consequence as well for the inclusion of this provision for 6500 programs will be more institutional style program expectations in a program which should increasingly exemplify the ideals of Everyday Lives principals in an integrated and typical family fashion to the retest degree. LifeSharing (6500) service providers are not currently required to complete the ODP Medication Training Module. The Module is necessarily a very detailed training requiring at least two full days of training plus four subsequent observations. This level of intensive training is possible in 2380, 2390 and 6400 programs because they have staff who are employees with employer-controlled schedules and they have centralized access to administrative supports, in perhaps a less intrusive way than entering a family's

home. These conditions do not exist and are not desirable for LifeSharing. LifeSharing is provided in people's homes.

LifeSharing providers are not employees who spend regular time at training locations, nor should they – they are typical families who work and live in the community. These families work their own independent jobs in the community and would be challenged just to have the physical access to go through this process. There is already a shortage of certified medication administration trainers contributing to this access problem. Requiring this additional training would necessarily result in losing some providers who are unable to connect with the available training times and places, and potentially separating an already established shared life situation with an individual. It would also add a new barrier for new family-providers at a time when the Department is trying to expand this service and providers trying to find and recruit willing families.

Another problem with this expansion of the Training Module into the 6500's involves the respite services which are crucial to helping LifeSharing providers to support individuals over the long-haul. Respite providers are often potential LifeSharing providers who are interested in gaining experience with the service and with individuals. These new/potential providers have not gone through full process as providers yet – adding this considerable step when they are not yet committed to the service would be destructive to the service.

Further concerns with requiring specific detailed training that can only come from service agencies to the 6500's is the necessity that we maintain LifeSharing providers' relationship as contracted supports rather than employees. The level of training specificity, the fact that it would be the "presumed employer" providing the training and the likelihood that LifeSharing providers would be taking the training alongside employees with no differentiation from the employees all implies an employee relationship which needs to be avoided if LifeSharing is going to continue to be an efficient, community-based model. Clear expectations are established by the IRS and DOL which providers must explicitly follow to maintain explicit differences between independent contractors and employees.

Finally, there is also a simple matter of proportionality. LifeSharing providers generally only serve one individual and the individuals in Life Sharing are typically able to take more responsibility for themselves than individuals in the other licensure groups. LifeSharing providers are able to focus-in on the needs of their lifesharer. They do not need days of general information. To require the Medication Administration Module of them would be disproportionate to their task – in fact, it would change the nature of the service from family-like supports to medical-model "administration" of medical care.

**Also applies to 2380.122, 2390.192**

**Citation: 6100.467. Medication Errors**

**Recommendation:** Medication errors should be handled according to the ODP's approved Medication Administration Training.

**Also applies to 2380.127, 2390.197**

**Citation: 6100.468. Adverse Reactions**

**Recommendation:** Adverse reactions should be handled according to the ODP's approved Medication Administration Training.

**Also applies to 2380.128, 2390.198**

**Citation: 6100.481. Department rates and classifications**

**Recommendation:** Subsections (a) (1) – (6) are not regulations but mere statements of possible future intent. Current state statute authorizes the Department to adopt regulations governing the provision of a payment for services such as HCBS. Separately, state statute authorizes the Department to contract with managed care organizations. A mere list of payment options serves no regulatory purpose and does not empower the Department to act beyond what it already may do.

**Citation: 6100.482. Payment**

**Recommendation:** The Department is obligated to pay for HCBS services consistent with the provisions of this chapter 6100. To the extent that the Department seeks to impose any of the provisions of "waiver amendments" or the state plans as mandates, those provisions must be adopted as regulations in accordance with the Commonwealth's regulatory review and approved process.

**Citation: 6100.571. Fee schedule rates**

**Recommendation:** The proposed regulations reflect a statement of intent as opposed to establishing an enforceable standard of practice by the Department and fails to explain the precise methodology that ODP will actually rely upon to establish

payment rates. ODP's proposed text essentially carries forward the worst elements of Chapter 51 – vagueness, unfettered discretion and lack of an affirmative duty to establish payment rates consistent with federal law (42 U.S.C. §1396 a(a)(30)(A)).

Providers are entitled to predictability, reliability, and accountability in the rate setting process. Reliance on statements about “review” and “consider” along with the vague reference to “criteria that impacts costs” are too imprecise and contrary to the Departments legal obligation to develop payment rates that are sufficient to meet the costs that providers must incur to meet the needs of their waiver program clients.

Instead, regulations should state the requirement to rebase rates every year based upon the inflation rate and the home health market basket index.

**Citation:** 6100.669. Other allowable costs

**Recommendation:** Where a Provider in good faith challenges Department action and the parties resolve the dispute and so avoid the cost and uncertainty of time consuming litigation for both parties, the legal fees and costs incurred by the provider must be recognized.

**Citation:** 2390.33. Program Specialist

**Recommendation:** The educational and experience requirements for a program specialist should be aligned throughout the chapters. As such, the specific field requirements for a Program Specialist in 2390.33 should be removed. Extensive experience in the field and working for providers under these regulations should be heavily considered in the qualifications for the program specialist role.

**Also applies to 2380.33**