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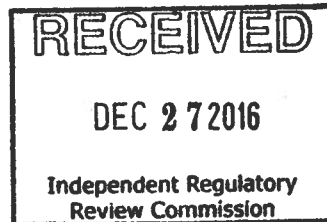
Kroh, Karen

From: Mochon, Julie
Sent: Tuesday, December 20, 2016 4:02 PM
To: Kroh, Karen
Subject: FW: Regulation 14 – 540
Attachments: 6100 final pc comments 16 12.docx

From: Paul Coleman 1 [<mailto:pc1@lifepath.org>]
Sent: Tuesday, December 20, 2016 3:39 PM
To: Mochon, Julie
Subject: Regulation 14 – 540

Hello Ms. Mochon,
Thank you for incorporating the attached comments into the 14-540 comment process. Please let me know if any problems with the document.

Sincerely,
PAUL COLEMAN





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Kash, Karen

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 DEC 2 2016
 Independent Regulatory
 Review Commission



December 19, 2016

Julie Mochon

Human Service Program Specialist Supervisor

Office of Developmental Programs

Room 502, Health and Welfare Building

625 Forster Street

Harrisburg, PA 17120

Re: Comments on Regulation 14 – 540

Submitted by Paul Coleman, CEO LifePath

Thank you for the opportunity to provide comment on regulation 14-540. LifePath provides services for over one thousand individuals in the Lehigh and Delaware Valleys who will be directly impacted by these regulations. The regulations include many laudable components. There are however, areas where the regulations continue to conflict with prevailing law. There are also areas where the Draft addresses issues in such proscribed specificity that it interferes with its own intents or prohibits larger consideration or utilization of current best-practices. In many places the regulations create additional unnecessary burdens. ODP leadership rightly espouses a vision that is not congruent with the effects of many of these elements. We understand that the Draft reflects a difficult consensus-building process involving many stakeholders, but the final regulations need to reflect more forward-looking thought than is represented in the current draft. These comments are submitted in hope that these regulations can become more helpful to all stakeholders.

Chapter 2380

PAR has submitted comprehensive comments on the sections of the 2380's which have been modified by the proposed regulation 14-540. Many stakeholders however, were disappointed that some sections of the existing 2380's which do not support the aims of community integration re the CMS community rule were not addressed (not included) in the new regulation. Our hope is that by opening up the 2380's for review in 14-540, it is still possible to address the following:

§ 2380.52. Indoor Floor Space

Current Regulation:

(a) There shall be at least 50 square feet of indoor floor space for each individual. Indoor floor space shall be measured wall to wall, including space occupied by equipment, temporary storage and furnishings. Space occupied by lavatories, dining areas, loading docks, kitchens, offices and first aid rooms may not be included unless it is documented that the space is used for programming for at least 50% of each program day. Hallways and permanent storage space may not be included in the indoor floor space.

(b) The indoor floor space square footage requirements specified in subsection (a) apply to each separate program area and room within the facility.

Discussion:

Spending money on floor space is certainly counter to ODP's goals. This element could be stricken, or modified for, "when individuals are present", but in truth, the entire section from 2380.52 through 2380.93 is about physical site and protecting people from risks such as portable heaters, poisonous cleaning products and flammable materials which are common in the community. It is necessary to impose these standards only for the number of individuals present at any one time, rather than total capacity as is the current interpretation.

These sections point to the need for high-level communication with BHSL, administrative entities, supports coordination providers and ODP Quality Assurance personnel regarding the new direction ODP is taking: providers didn't choose to set up institution-like services, regulations like these coupled with facility-focused licensors and QA processes focused on preventing harm have led us all to set up environments which protect people from risks rather than expose them to the real world. Progress towards integration will require that perspectives are changed as much as the regulations themselves.

Proposed: "(a) There shall be at least 50 square feet of indoor floor space for each individual present."

§ 2380.121. Storage of Medications.

Current Regulation:

(b) Prescription and nonprescription medications shall be kept in an area or container that is locked.

Discussion:

Programs do use lock boxes when going into the community, but following people around with lockboxes (or coolers large enough to contain lock boxes) does not increase integration. Nor does having to run back to a facility for "Med Time". Language could be added to this regulation or to an interpretive guideline such as, "except when people are in the community" to increase integration.

§ 2380.131. Dining area.

Current Regulation:

(a) The facility shall have a dining area for lunches and breaks. The dining area may be a program area as long as the area is not used for purposes of programming and dining at the same time.

Discussion:

As with other physical site requirements above, this may not be necessary for people integrating into the community and should be re-written to that effect or deleted.

Chapter 6100

§ 6100.45. Quality management.

Discussion:

There are numerous models of quality management that a corporation might choose for itself. Valid models include accreditation processes such as CARF, Six Sigma, Quality Report Cards and many others. The content of a free-standing corporation's quality management plan needs to be determined by that corporation. The Draft is problematic, in both, 1) its level of proscription (which includes 9 specific elements *in addition to* the department's "criteria and priorities") and 2) in the 9 elements themselves.

- 1) A *requirement* for 9 elements in a quality management plan is excessive and burdensome and will generate additional unnecessary diversion of resources from service provision to administrative cost. The quality management plans of the nation's best corporations focus on the handful of elements that are most relevant to that

corporation. A strong quality management plan is focused and specific - not a long checklist of required elements. Over-proscription also delimits content: What if the most relevant elements for a corporation are not on this list at all? Individual safety, facility maintenance, strategic planning goals, external benchmarking and many other valid components of a QM plan are not represented in this draft. The point is not to add these items to this already lengthy list. The point is to allow providers the independence to determine what their own QM plans should include. True quality improvement will not be accomplished by the creation of more paperwork.

Recommendation § 6100.45(b):

“...conduct a review of performance data in the following areas...” should be changed to read, “...conduct a review of performance data in areas such as the following...”

- 2) Regarding the elements themselves, aside from their overly proscriptive nature, some of them are not appropriate. 42 CFR § 441.302 pertains to the state’s own assurances to the federal government (e.g., “Assurance that the (state) agency's actual total expenditures for home and community-based and other Medicaid services under the waiver and its claim for FFP in expenditures for the services provided to beneficiaries under the waiver will not, in any year of the waiver period, exceed 100 percent of the amount that would be incurred by the State's Medicaid program for these individuals, absent the waiver, in—(1) A hospital; (2) A NF; or (3) An ICF/IID.” This is a state-wide fiscal management item, not a provider-based quality assurance element. How would a provider address state expenditures in a quality management plan? This is an example of the Draft confusing the state’s own responsibilities with those of providers.

Recommendation § 6100.45(b),(3):

Eliminate reference to 42 CFR § 441.302.

Another burdensome, invalid and counterproductive element here is *the requirement* for staff satisfaction survey results. Staff satisfaction surveys were common in the 1980’s and have been largely discredited and often found to be counter-productive and even discriminatory (Heckman et al 2009, Forbes, April 2014, May 2012). Satisfaction has been found to be something that people bring to work, not something created by employers. Attempts at satisfaction measurement have not been found to be valid (Isen, 2002, 2003) and are often irrelevant to actual performance (Hulin and Judge 2003). Even the portions of the HR consulting industry that still promote staff surveys (against the empirical results of numerous studies) have in large part moved on to attempt to measure staff engagement rather than satisfaction. Staff satisfaction surveys are certainly not something the state should mandate. Once again, the point is not to

add another element to an already unwieldy and burdensome regulation, but to allow providers as independent corporations to manage themselves.

Recommendation § 6100.45(b) reiterated:

“...in the following areas...” should be changed to read, “...in areas such as the following...”

§ 6100.54. Recordkeeping.

(b) A provider shall not make participant records accessible to anyone other than the Department, administrative entity, support coordinator or targeted support manager without the written consent of the individual, or persons designated by the individual.

Discussion:

This conflicts with federal HIPAA and ACA law and Pennsylvania’s own Act 148. Existing law deals with this issue in much more specificity and depth. Numerous other legal, medical and administrative entities such as the CDC have access to records regardless of individuals’ consent. This section is also in conflict with DHS’s own requirements for agencies to perform external audits and the auditing practices of agencies such as the Social Security Administration. These laws and practices are subject to change over time and take precedence over DHS regulation.

Recommendation § 6100.53(b):

Replace § 6100.53(b) with “(b) Providers will work to preserve confidentiality as they comply with all applicable laws and authorities.”

§ 6100.303. Reasons for a change in a provider or a transfer.

(a) The following are the only grounds for a change in a provider or a transfer of an individual against the individual’s wishes

Discussion:

There are numerous legitimate grounds for provider changes or transfer of an individual which are not listed in the Draft. Program closure, the safety of others, Megan’s Law, eviction by a landlord, eminent domain, license revocation, health concerns, necessary renovations and natural disaster are just a few. Adherence with CMS’s “Any Willing Provider” concept and CMS’s Community Rule (for instance, when the existing service is not adequately integrated into the community) are additional grounds which do not

consider individuals' wishes. The Draft again forgets that providers are independent entities whose legal rights and responsibilities exist in many laws reaching beyond these proposed regulations. Corporations must act in accordance with concerns beyond "the individual's wishes". Over-specificity / over-proscription is a problem throughout the Draft. Where this is untenable, such as in this section, it will lead to additional administrative cost in the form of disputes, renegotiation, appeals and legal action. These costs divert precious resources from service provision. This regulation is another attempt to create a right that does not exist for typical community members – as such, it ultimately will not prevail. The Community Rule provides appropriately for rights commensurate with the community.

Recommendation § 6100.303:

Replace this section with broader and practicable language such as, "PSP teams will make strong efforts to keep individuals' wishes central to changes in a provider and in transfer situations".

§ 6100.304

(b) If a provider is no longer able or willing to provide a support ...the provider shall provide written notice ... at least 45 days prior to the date of the proposed change in support provider or transfer.

Discussion:

This section does not speak to the numerous circumstances (some are listed in the immediately preceding 6100.303 comment) which require less than 45 day notice. The CMS Community Rule requires that individuals have tenancy rights equitable to other community members. This section exceeds this requirement.

Recommendation § 6100.304(b):

Replace § 6100.304(b) with "Providers will give notice to the individual, persons designated by the individual, the PSP team members, the administrative entity and the support coordinator or targeted support manager and the Department in accordance with the Department's Room and Board Contract."

§ 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 incidence of access.

Discussion:

This regulation in its over-specificity does not consider numerous valid situations in which it may be desirable or necessary for people to access an individual's bedroom. Many individuals require repositioning during the night, in-sight monitoring as per their PSP, physical assistance in transferring in and out of bed, assistance responding to fire drills or other services that do not meet the life-safety emergency threshold. Many of these same individuals are not able to express permission or give consent. CMS in its Public Notice and Comments to 42 CFR Part 441 addresses this and states "The person-centered planning process and plan should address the circumstances in which this might happen."

Recommendation § 6100.443:

Replace (f) with, "Access to an individual's bedroom shall provide for privacy to an individual except in emergencies or as stated in the PSP."

§6100.461 through 6100. 469 all pertaining to MEDICATION ADMINISTRATION

Discussion:

PAR's Comments and suggestions regarding the sections addressing Medication Administration are extremely apt and important. These sections of 14-450 have many negative ramifications. We have included PAR's content below for reference. We propose an alternative recommendation to replace the existing proposed regulation. Our recommendation eliminates the need for all of the separate sections. For instance, the Department's Medication Administration Training program already addresses Self Medication.

Recommendation §6100.461 through 6100. 469:

"6500 programs shall follow the sections of § 6500 pertaining to medications. 2380, 2390 and 6400 programs shall follow the Department's Approved Medication Administration Training program for Oral-route medications and will follow published Department guidance regarding other medications."

(PAR) Comment and Suggestion: Medication Administration

There are two extremely important issues concerning the proposed new regulations pertaining to medication administration. These issues must be carefully reconsidered by the Department.

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 contrast 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.

For all of these reasons, and based upon years of provider experience and informed by ID/A professionals and experts, PAR strongly recommends and urges the Department to delete the sections of the proposed regulations noted below and to require instead compliance with the Department's approved Medication Administration Training module.

Comment and Suggestion 6100.462:

It appears that there was an inadvertent problem created by the inclusion of standardized medications content across these four program areas that includes the 6500 regulations. If the 6500 LifeSharing

programs are included in this requirement, significant unintended consequences are likely to arise and cause severe negative impact on the viability and expansion of this program – a program that the Department has repeatedly stated it desires 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 retent 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.

Particularly with an aging population, the Department should consider permitting the administration of oxygen, breathing treatments, catheterizations, tube feedings, and similar treatments.