

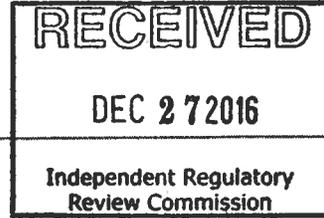
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14-540-266

**Kroh, Karen**

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**From:** Mochon, Julie  
**Sent:** Tuesday, December 20, 2016 4:03 PM  
**To:** Kroh, Karen  
**Subject:** FW: Regulation No. 14-540  
**Attachments:** Susan Lautenbacher - 6100 Regulations.docx



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**From:** Susan Lautenbacher [mailto:SLautenbacher@Larkent.org]  
**Sent:** Tuesday, December 20, 2016 3:50 PM  
**To:** Mochon, Julie  
**Subject:** Regulation No. 14-540

Dear Julie:

Please accept the attached document as our written comments concerning the 6100 regulations (Regulation No. 14-540).

Thank you,

Susan Lautenbacher, Ph.D.  
Chief Executive Officer

*Helping Individuals Become Self-Reliant and Integrated into the Community*



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Independent Regulatory  
Review Commission

Susan Lautenbacher, Ph.D., CEO, Lark Enterprises, Inc. – Comments and Recommendations for the 6100 Regulations

Section	Comment/Recommendation
General comment	I would like to take this opportunity to thank and acknowledge the hard work that was put into the writing of the 6100 regulations. Many of the concerns I have heard over the last several years have been addressed within this document. The 6100 regulations proposed by ODP on November 5, 2016 are an improvement and a step in the right direction. There is a consistent focus on person-centered outcomes based on personal preferences. However, there are numerous questions, comments, and suggested edits we here at Lark would like ODP to consider.
<b>General Requirements</b>	
6100.42	Monitoring Compliance – (a) – This states that the department and the designated managing entity may monitor compliance with this chapter at any time through an audit, provider monitoring or “other monitoring method”. This is very open-ended. Please add the words, “department pre-approved” after “other” and before “monitoring.”
6100.42	Monitoring Compliance – (e) – Please strike “alleged violation”. It is not clear why a provider would have to do a plan of correction for something that was merely alleged. If the allegation is unfounded, then there is nothing to correct.
6100.43	Regulatory Waiver (a) – It is a concern that waivers are not permitted for positive interventions or rights. For example, not allowing a waiver impacts services that are provided to individuals who are sexual offenders, or for people with lifelong medical conditions like Prader-Willi. When supporting people with problematic sexual behavior or someone with Prader Willi, rights must be restricted. Individuals with PBS come into the program with the understanding that they cannot access some public places or need to leave if they display behavior associated. Individuals with Prader –Willi live with food locked up. Another example is when supporting an individual who use their personal property to self-injure. Sometime access must be limited and use monitored. Individual who insert objects into all orifices of the body and do great damage. These objects are often their personal property and waivers are necessary to limit access. Please change this section to address these circumstances, and please permit for a serious health concern to which the individual and their team consent.
6100.43	Regulatory waiver - (c)(2) – Please change language to recognize that there are times when a waiver may be requested that would infringe on community integration, independence, etc. because of health, safety and well-being issues.
6100.43	Regulatory waiver - (f) – This makes no sense as written. If the request involves the “immediate protection of the individual’s health and safety”, and the provider has to submit the written waiver request at least 24 hours to the individual and individual’s designee prior to actually requesting the waiver, then the provider is unable to protect the individual’s health and safety

	<p>“immediately”. Immediate means immediate. Please consider adding an exception, or rewrite to allow a “presumption of waiver” with an immediate follow up to formally secure the waiver.</p>
6100.44	<p>Innovative project - The introduction of Innovation projects is very positive, as it will allow for ideas that might not fit cleanly in the definitions. This is an excellent way to enable providers and families to pioneer new programming that could advance the development of best practice that better serve individuals with disabilities. Also, while it is good that the 6100s will allow innovation, it may be a moot concept if there is no permissible avenue to use waiver funding to cover the cost of the new service or program. ODP should explain how innovation projects will be paid for, either through the waivers or separate fund. Also, as a general matter, there is significant concern with all of the requirements spelled out that “must” be included in a project proposal. Instead of saying “must”, please consider saying “must include sufficient information on which a prudent and informed decision can be made by the Deputy Secretary. As much or all of the following information should be provided:” It will be in the provider’s best interest to submit as much of the information as possible. However, there may be certain information that simply is not available or not worth developing and submitting given the nature of the project. The Deputy Secretary is under no obligation to approve the project as submitted, and if he or she believes certain key information is lacking, it can be returned for fine tuning.</p> <p>These comments appear as they do in the comments from RCPA as I could not find better words to communicate my feelings and those of my staff.</p> <p>Innovative projects allow us to move the field forward in creative ways that ultimately best serve people with disabilities, funding sources, organizations and the community as a whole. Life is continually changing and new and better ways emerge over the course of time. Innovative projects will allow us to move in concert with life’s changes.</p>
6100.45	<p>While we are strong supporters of Quality Management we do have some concerns that mirror those of other agencies. Our capacity to reach greater levels of data collection and analysis as reflected in the 6100 regulations is greatly compromised by the size of our staff. Data helps to ensure the level of quality we desire to always reach as an agency, but we must balance quality of data and quantity of data in order to use our resources in such a manner to ensure quality at all times.</p> <p>Quality Management – General comments. Areas of performance data have been expanded in the 6100s. Although the data will be beneficial, it will require more staff time, tracking tools and sophistication for all agencies. Rates do not include the additional staff time and tracking tools. Larger agencies may have staff to provide quality management, but smaller agencies will have to add responsibilities to already overburdened staff.</p> <p>Also, these requirements are too prescriptive. Please consider using them as examples of what can go into a QM plan, but do not require them.</p> <p>Also, at a minimum, ODP training is needed for providers on trend analysis,</p>

	<p>how to analyze and successful learning and application of training, systemic improvement, and measures to evaluate the success of the plan.</p> <p>Also, providing examples of low-cost tracking tools or ones that are developed as a statewide initiative will be helpful.</p> <p>ODP has issued a QM Bulletin with requirements for the areas providers must address in their QM plans, and it was based on state priorities – please clarify whether that bulletin still be applicable.</p>
6100.45	<p>Quality management – (b)(1) – This should be clarified or deleted as it is not measurable. Measuring every possible outcome contained in an individual’s PSP is impossible. There are not enough resources in the system to do this.</p> <p>Also, it is not clear how a provider would measure. It is not clear whether it need to be done for every person served by the agency. It is not clear whether it would be done by service (e.g., an individual could receive several services from one provider and make progress in residential goals, but not in their vocational goals, etc.). It is not clear whether trying to simply preserve skills as a person ages would be considered “progress.” It is not clear whether it means progress in the utilization of units or an individual’s actual progress to goal outcomes.</p> <p>Also, please clarify whether outcomes will be or should be standardized? Experience shows that SCs develop outcomes that range from “Tom has a competitive job” to “Tom will earn money to do the activities he enjoys.”</p>
6100.45	<p>Quality management - (b)(3) – Please clarify whether this will mean the provider still determines the goals in their QM plan or whether the state will now say exactly what the goals will be that the provider needs to work on. Also, please include the list of state assurances included in 42 CFR441.302. Also, please clarity how (3) is different than (9).</p>
6100.45	<p>Quality management - (b)(5) – Please include a minimum frequency standard.</p>
6100.46	<p>Protective Services - (b) – When it says “until...the investigating agency has confirmed that no abuse occurred”, please clarify what happens if the investigation is inconclusive, which agency is meant, and what happens in the event that different “agencies” come to different conclusions (e.g., agency doing a certified investigation vs. protective services agency).</p>
6100.47	<p>Criminal history checks – (d) – Please consider rewording as follows: “Individuals providing paid or unpaid supports with direct contact with the individual in services.” If the department keeps the “natural supports” reference, please consider changing to “Individuals delivering natural supports”. Also, there is a concern whereby a family member (who is providing natural supports) could be a convicted sex offender but it is unknown to others – this person would seemingly be exempt from having to get a criminal history check. Also, natural supports can also include volunteers (e.g., a local church group helping an individual get to and from church every Sunday). Please clarify whether (b)(5) of this section would trump (d).</p>
6100.48	<p>Funding, Hiring, Retention, and Utilization - (a) – This requires hiring in</p>

	<p>accordance with the applicable provisions of the OAPSA. However, the court held some of these hiring provisions as being unconstitutional on its face. Please provide clarity in the regulations which provisions are applicable. (Peake v. Commonwealth 2015; Nixon v. Commonwealth 2003)</p>
6100.52	<p>Rights Team - This section has also been commented on by RCPA and The Provider Alliance. I would encourage a close look at this section as it is already addressed in Incident Management and the redundancy does not add to the process but could possibly detract from it due to the burdensome nature.</p> <p>Rights Team – General comment – 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 has 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.</p> <p>Also, this is a new requirement that will add a significant amount of time that staff are not engaged with individuals in service. The team must review each incident, alleged incident and suspected incident of a violation of individual rights, review each use of restraints, analyze systemic concerns, design positive supports as an alternative to the use of restraints and discover and resolve the reason for an individual’s behavior. This is going to require a highly trained staff (Master’s level) trained in behavioral sciences. Also, please consider building these requirements in to the quality management plan instead of creating something new.</p>
6100.52	<p>Rights Team – (a) - In the chapter 6400 regulation changes, the statement is made that “the home must have a human rights team”, whereas in the 6100s it says the agency must have a team. Please clarify.</p> <p>Also, the creation and role of a “Rights Team” seems to overlap if not duplicate the requirements of the Restrictive Procedure Review committee (see for example 6400.194). Please consider not creating something new. Please consider allowing providers to amend their Restrictive Procedure Committee to meet the needs of 6100.52.</p>
6100.52	<p>Rights team (b)(1) – General comment - Having a meeting of the rights team for each incident, alleged incident and suspected incident of a violation of rights is going to be problematic, because the rights are so broadly drawn. For example, 181(b) “an individual shall be continually supported to exercise the individual’s rights”, while sound philosophically, is incredibly vague and open to interpretation, and fails to take into account the individual’s functional ability. The same problem exists with (c) an individual shall be provided the support and accommodation necessary to be able to understand and actively exercise the individual’s rights. It is one of those regulations that will be almost impossible to validate for compliance without becoming extremely burdensome. Considering that violation of rights is also an incident which must be reported, the regulations would now require that an allegation of</p>

	<p>rights violation be reported as an incident, investigated by a Certified Investigator, and the reviewed by a rights team consisting of the Provider, the individual, the SC, an AE representative. Interpretations have often differed on what constitutes an incident, so in the example of 181(c), an SC could decide that a provider has allegedly violated an individual's rights by not allowing him/her to drive a forklift as desired even though he/she is legally blind, cannot drive and would pose a hazard to others. Yet the individual has under 6100.182 (e) has the right to make choices and accept risks. While the example seems to border on the absurd, providers have had similar types of situations. One SC identifies his/her responsibility to support one particular individual without regard to how it affects others. And a lot of time, energy and money is wasted by a provider in defending themselves.</p> <p>If this section is kept intact, please replace "alleged" with "founded". Often reports are made by disgruntled employees, or perhaps an individual who enjoys the attention paid for making allegations that are not founded. Keeping "alleged" would end up taking time and resources from needed service time, and may have an unintended result of giving more attention to a negative behavior. Such issues are best dealt with by the PSP team.</p> <p>Also, please clarify whether this section includes individual-to-individual incidents.</p>
6100.52	Rights Team – (b)(2)(i)(ii)(iii) – Please reconsider these provisions. This is not the role of a rights team. Furthermore, it would take up excessive time. This is the role of a behavioral supports professional, psychologist, etc., working with the individual, etc. A rights team is to look at rights violations. It would be better to have a provider behavioral interventions review committee to take this on (e.g., meeting every 3 months) and then have a human rights committee that reviews rights violations, any restraints in terms of rights violations, etc. (meeting every 6 months).
6100.52	Rights Team – (b)(2)(iii) - In some instances, the reason for an individual's behavior cannot be discovered. However, potential causes can be identified. Please reword to allow for more practical application of the requirement.
6100.52	Rights Team - (c) – Please consider changing this from requiring that an individual be part of the team to considering it on a case by case basis as recommended by the PSP team and/or allowing an exception if including the individual is likely to be detrimental to them. For example, including the individual in the team could re-traumatize an individual who has been abused by making them recount the experience. This should be something that is considered on a case by case situation and recommendations of the PSP team.
6100.52	Rights team - (d) – Please consider adding language that ensures the confidentiality of the individual. Having a majority of the members of the team be those who do not provide direct support to the individual will make it difficult to ensure confidentiality.
6100.52	Rights team - (f) – Please considering "if there are incidents to review" to this provision. As written, requiring the team to meet at least once every 3 months is going to be burdensome. These meetings will be in addition to the PSP

	meetings! This requirement is not consistent with having an “everyday life”. Nobody else in society is required to have so many meetings about their lives. Also, this is an unfeasible requirement since it will be impossible in all cases to get family members together.
6100.54	Record Keeping – general comment – Please consider making it clear that electronic records are allowed and recognized.
6100.54	Record Keeping – (b) – Please review this statement in the context of whether it aligns with HIPAA. For example, HIPAA requires that records be released to certain entities under certain circumstances that are not identified in this section, such as courts or other legal entities, the Department of Health, the CDC, etc.
<b>Enrollment</b>	
6100.86	Delivery of HCBS – general comment – Please clarify that this section is not intended to limit a provider’s ability to conduct private-pay business, and that these provisions are applicable only to services funded by waiver, state plan, or base funding.
<b>Training</b>	
6100.141	General comments. It is positive that there will be greater consistency to the training requirements. Also, it is positive that the training is intended to provide more protection for the individuals served. Also, it is positive the mandatory training requirement topics (e.g., the removal of the requirement to train on ODP’s mission and vision) have been simplified and/or reduced and providers have been given greater control over the orientation and annual training plans. Also, there are concerns about instituting very specific requirements in relation to exact “8 hours” of training on the core areas and 12 overall. It is recommended that ODP simply require that providers meet the requirements of the core training and completing 12 hours (and remove the 8 hours on the core training specification). Also, there is a concern that the training requirements will discourage volunteers. Also, there is concern that these requirements will require additional funding and resources that ODP is not making available. Grateful
6100.141	Annual Training Plan – (a) – Please clarify that this does not mean that every staff member must have a personalized training plan; rather, a provider may look collectively at the overall needs of the individuals and develop training around the greatest needs/topics based on data, overall quality management goals, etc.
6100.141	Annual Training Plan - (e) – Please define “core competencies” so that it is not left up to interpretation by the AEs.
6100.141	Annual Training Plan – (e) – Please include a timeframe when it comes to how long training related records must be retained.
6100.142	Orientation program - (a) – Please clarify if this regulation is really intending to mandate training and the tracking of training for all the listed categories of staff. If so, please clarify the purpose. It is recommended that all categories of

	<p>people who do not have direct contact with individuals and/or are involved in the development or implementation of services to individuals be deleted from this requirement. Also, please clarify if management staff of agencies that provide other lines of services, such as behavioral health, are also included in the requirement. Please clarify if fiscal staff who are in a totally separate building from any client program are included in the requirement. Also, this entire section of the 6100s has also been inserted into the licensing regulation sections (see 6400.50-52). As such, please clarify if this mean a provider would have to produce training plans and records for all of these categories of staff during an inspection by BHSL.</p>
6100.142	<p>Orientation program - (a)(8) – Please clarify who is responsible for assuring that consultants have training – especially those that bill directly to ODP (e.g., the SC?).</p>
6100.142	<p>Orientation program - (b)(1) – Please clarify whether there will there be specific training guidelines for each of the areas specified.</p>
6100.143	<p>Annual Training - (b) – It is recommended that if DHS insists that all non-direct care staff must have specific topics (e.g., reporting of abuse), then the regulation address the topics required, but not the amount of time. The length of time a training should be should not be specified. People learn at different rates, and the important issue is that they understand the topic, not the amount of time spent. This would be true for volunteers and interns as well, especially since they may have a limited amount of time to spend with an agency – it could discourage involvement if the amount of training time is cumbersome.</p>
<p><b>Individual Rights</b></p>	
6100.182	<p>General comment – Generally and overall, the changes to these rights are positive - they were in need of being updated. However, there is concern that many of the rights articulated cannot be regulated because they are too subjective (e.g., dignity and respect). Providers already complete Civil Rights surveys and maintain non-discrimination policies as part of licensure and monitoring. This section could require duplicative policies, procedures, training, and documentation.</p>
6100.182	<p>Rights of the Individual – (f)(g)(i) – Please consider allowing exceptions for individuals with special circumstances when it comes to individual health and safety and community safety.</p>
6100.182	<p>Rights of the Individual - (f) – While we strongly support the philosophy of this provision, please clarify how this provision is supposed to be implemented in light of the department’s plan to eventually require all individuals in day program to spend at least 75% of their time outside of a licensed facility (e.g., if one person refuses, and there isn’t staff to take the others, wouldn’t the rights of the others be violated?). Please consider modifying the language so that, if the individual does agree to enroll in a group community participation service, then they are committing to participate in those activities. If the individual is not interested in a group activity, then he/she should reduce or discontinue services, so as not to affect programming for other individuals in that service.</p>

6100.82	Rights of the Individual – (g) – While we strongly support the philosophy of this provision, there is strong concern about how, as a practical matter, this will play out in the real world. Again, please consider how a provider is supposed to meet the requests of three individuals who all want to participate in different activities in the community at the same time when the rate cannot support triple staffing. And please clarify whose rights in that case are to be honored when 3 individuals want to pursue 3 different schedules.
<b>Employment, Education, and Community Participation</b>	
6100.261 6100.262 6100.263	General comment – While it is recognized that this section is an attempt to incorporate the CMS HCBS Rule and WIOA into the 6100s, please clarify how a provider’s compliance with these will be evaluated or measured. For example, in 6100.263 – please clarify how a provider ensures that an individual has “access to a full range of options...in...post-secondary education”, unless the provider only needs to be concerned with (3) Lifelong learning.  Also, the department should ensure the funding necessary for individuals to access the community in accordance with the individual’s PSP.
6100.262	Employment - (a) – After the word “shall”, please insert “be given information about competitive, integrated employment as well as information about resources that could assist the individual in their pursuit of competitive, integrated employment. If the individual wishes to pursue competitive, integrated employment, the individual shall”
6100.262	Employment - (b) – As written, this reflects current service definitions. As proposed, ODP’s waiver renewals will no longer have prevocational as a service. Either strike the provision and leave it for the waiver, or insert after “prevocational” the words “, pre-employment, or skill development”, and after “support” insert “provided in a licensed facility such as a vocational facility”.
6100.263	Education - In the third line, please change “have access to” to “be given information about, and supported if chosen,”
<b>General Payment Provisions</b>	
6100.482	Payment - (c) – There should be an allowance for flexibility in the frequency and duration statement.
6100.482	Payment - (c) - There should be a provision for services provided in an emergency (like respite) that are not yet authorized.
6100.482	Payment - (c) – There should be a provision for back-dating an authorization or frequency and duration change.
6100.482	Payment – (c) – It says the Department will only pay for reimbursable HCBS up to the maximum amount, duration and frequency. There should be greater clarity how this will be tracked or enforced.
6100.482	Payment - (h) - In the second sentence, it should say “or” instead of “and”.
6100.484	Provider Billing - (c) - see comments related to 6100.226 – we need specific and clear guidance on “documentation of support delivery”.
6100.487	Loss or Damage to Property - This should be clarified that the provider would

	replace the property if it is determined to be as a result of staff negligence, or some fault of the provider, and also allow for the repair of the item instead of requiring that items must be replaced.
<b>Fee Schedule</b>	
6100.571	Fee Schedule Rates - (a) - The language should be written to obligate the department to actually use rates that reflect whatever changes result from the refresh discussed in (b) (i.e., as written, the department seems to be able to refresh the data but then keep rates the same).
6100.571	Fee Schedule Rates (b) – RCPA is pleased that the department has proposed language that requires it to refresh the market-based data used to develop rates. However, instead of every three years, it should be done every year. Also, the word “refresh” should be changed to “rebase” or “rebased”.
6100.571	Fee Schedule Rates - (c) - Language should be added that requires the department to be transparent about the method it used to “consider” the factors indicated. Also, language should be added that requires the department to be transparent about the sources of data and information used. Also, if the department does not include language requiring an annual refresh (or rebasing) of market data, then the language ought to say the department will apply a cost-of-living adjustment based on the federal home health market basket index.
6100.571	Fee Schedule Rates – (c)(2) - Language should be added that requires the department to consider US Department of Labor and PA Department of Labor and Industry statistics for relevant industries, such as the health care industry, as well as labor statistics for non-health care or human service industries with which ODP-funded HCBS providers are in direct competition for workers (e.g., fast food, retail, etc.).

