CLASP
policy solutions that work for low-income people

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Dear Administrator Wakefield and Acting Assistant Secretary Hansell:

We are writing on behalf of the Center for Law and Social Policy (CLASP) in response to the proposed criteria for evidence of effectiveness of home visiting program models for pregnant women, expectant fathers and primary caregivers of children birth through kindergarten entry (criteria) published in the Federal Register on July 23, 2010 (Vol. 75, No. 141). We appreciate the opportunity to provide comments.

CLASP is a non-profit organization that develops and advocates for policies at the federal, state, and local levels to improve the lives of low-income people. We focus on policies that strengthen families and create pathways to education and work.

In collaboration with a number of other organizations that work on a range of issues impacting vulnerable children and families, we have advocated for the development of a federally funded home visiting program for a number of years. We worked closely with the Administration as it developed its home visiting proposal in the 2010 Budget Request. We also worked closely with key Members of Congress as various home visiting proposals have been put forward over the last few years with bi-

partisan and bi-cameral support, including the proposal that was ultimately included in the Affordable Care Act (ACA) passed earlier this year. Throughout these efforts , we emphasized the importance of creating a program that supports a variety of quality, evidence-based, voluntary home visiting models in order to reach as many eligible families as possible. We were pleased to see these elements reflected in the final legislation. This new federal grant program will provide states with important tools to promote greater school readiness, enhanced child health and development, improved parenting practices, reductions in child maltreatment and later criminality and will also help to link families to comprehensive services.

We appreciate the opportunity to comment on the proposed criteria particularly because we believe they are so critical to the success of the program. These criteria will help ensure , as provided in the law, that states have the flexibility to assemble home visiting programs that include a range of evidence-based and promising models in order to improve outcomes for children and families. These criteria are also essential to ensuring that the ultimate goal of the program – establishing a coordinated system of early childhood home visitation in every state with the capacity, infrastructure and supports to assure high-quality, evidence-based practice – is realized.

There are a few areas where we think the criteria need to be modified to ensure that the program moves forward in a way that is consistent with the law and in a way that will help ensure positive outcomes for the children and families served through the new program. We realize that these modifications may prolong the process somewhat and recognize that there is great need to release the remainder of the dollars as soon as possible so that states can start serving children and families. However, we think that it is critical to clearly establish the foundations of this program from the outset rather than moving forward quickly with criteria that may have unintended negative consequences.

1. Eliminate the "high," "moderate," and "low" ratings of studies and simply delineate those which are "evidence-based."

In the ACA, which authorized the Maternal, Infant, and Early Childhood Home Visiting Program, Congress committed $1.5 billion over five years for the provision of home visiting services. Seventy-five percent of the funding is dedicated to those models of home visiting that are "evidence-based," while up to twenty-five percent of the funding can be used for models of home visiting that offer "promising approaches" to reaching vulnerable children and families. The statute explicitly defined "evidence based" home visiting models to include those with positive outcomes, as documented by both well-designed and rigorous randomized controlled trials (RCTs) and well-designed and rigorous quasi-experimental designs (QEDs).

Although there are distinctions to be made between RCTs and QEDs in terms of research and some have indicated a preference for RCTs in a purely scientific setting, CLASP firmly believes the QEDs and observational research provide equally important information to develop and implement evidence-based policy. There are two basic reasons for our position. First, there are certain things that simply cannot be tested with RCTs. For example, subjecting certain interventions to RCTs would be

considered unethical by many. Consider a study in which the researcher wanted to test whether children who are found to be victims of child maltreatment can remain safely at home if they are provided with services. To meet the criteria of a RCT, children determined to be in situations with the same risk of re-abuse would have to be randomly assigned to remain at home with services or to remain at home with no services. Good casework, common sense and the obligation to protect children from harm all rule out such an experiment.

Second, there has also been broad acknowledgement that multi-faceted approaches designed to impact families, often through behavioral change, are not well evaluated using a RCT approach, particularly when those families are in at-risk communities. For example, RCTs may serve to limit the ability of programs to respond to the unique needs of differing populations they serve and to implement a holistic approach. They also provide little information about what it takes to combine multiple interventions to achieve stronger outcomes or to scale up such layered, comprehensive approaches to working with children and families. In describing the Harlem Children's Zone, an approach that has significant support from this Administration, Lisbeth Schorr, a Senior Fellow at the Center for the Study of Social Policy and a lecturer in social medicine at Harvard University, eloquently explained: "Harlem Children's Zone itself has been described as an endeavor that 'meshes educational and social services into an interlocking web, and then it drops that web over an entire neighborhood.' We won't find interlocking webs or web drops in the directories of evidence-based programs, now or ever. Nor is the problem solved by evaluating the impact of each discrete program, because the entire point of efforts like the Harlem Children's Zone is that we expect the whole to have a far greater impact than the sum of its parts."[1]

The definition of "evidence-based" in the legislation creating this home visiting program recognizes the value of both RCTs and QEDs in developing and implementing policy and quite intentionally included both well-designed and rigorous RCTs as well as well-designed and rigorous QEDs in the statutory definition of "evidence-based." While the debate over the respective merits of RCTs and QEDs may persist in the research community and in thinking about crafting policies in the future, for the purposes of this home visiting program, the debate was clearly put to rest. It is important to remember that while the final home visiting language may have seemed largely ignored in the broader health care reform discussions, significant attention was paid to crafting the language defining "evidence-based." The language represents not only the very intentional work of the legislative champions of the program but also the broad consensus of home visiting models and advocates.

It is also important to note that while the ACA required HHS to establish *criteria* to facilitate implementation of the Home Visiting Program (Sec. 511(d)(3)(A)(iii)), it did not give HHS the authority to limit the *definition* of "evidence-based" beyond that provided in the law (Sec. 511(d)(3)(A)(i)(I)). This important distinction was highlighted in a recommendation made by the Home Visiting Coalition in a letter to HRSA and ACF dated April 8, 2010. In that letter, CLASP along

[1] Schorr, L. "To Judge What Will Best Help Society's Neediest, Let's Use a Broad Array of Evaluation Techniques." The Chronicle of Philanthropy August 20, 2009 *available at: http://philanthropy.com/article/To-Judge-What-Will-Best-Help/57351/*

with the other members of the Home Visiting Coalition, including five national home visiting models, recommended that, "the regulations regarding the criteria for evidence of effectiveness of the models required by Sec. 511(d)(3)(A)(iii) be consistent with the important detail on the criteria for effectiveness of service delivery models that is already in Sec. 511(d)(3)(A)(i)(I)."

Therefore CLASP believes the proposed criteria are inconsistent with the legislation when they make distinctions between these two study designs and give one design a designation of "high" and the other a designation of "moderate". This is particularly true if the funding is tied to these designations with states that select models with RCT studies being awarded more points in a competitive grant process as is suggested in Section 7. Even if the rankings are not tied directly to funding allocations, we remain concerned that the ranking will suggest to states that they are better served by selecting models with RCT studies and discourage them from selecting models that might provide more insight into implementing programs on the ground for broad populations, or that might better meet the needs of unique communities of vulnerable families in a particular state, as indicated by the statewide needs assessment.

Therefore, CLASP strongly recommends eliminating ranking of quality of studies as "high" "moderate" or "low" as is suggested in Section 3.1, and simply delineating those which are "evidence-based."

2. Continue formula funding of grants rather than layering a competitive grant structure on top of the formula funding.

In authorizing the home visiting program, the ACA did not specify whether the program was to be funded on a formula basis or through competitive grants. We are pleased that the Health Resources and Services Administration and Administration for Children and Families (HRSA/ACF) elected to utilize formula grants as this helped to more quickly get the funds to states so they can begin moving forward. In particular, we are pleased that HRSA/ACF allowed states to use the first $500,000 of their allocation for planning or implementation activities, including conducting the required needs assessment. We are concerned, however, that layering a competitive grant process on top of the formula grant for years two through five will make it difficult for states to plan and effectively scale up their programs. If the increased funding in the second through fifth years of the program are subject to annual competition, states will not be able to easily anticipate what funding they will have from year to year and thus will not be able to develop a sustainable plan for expanding the program in an orderly manner to achieve positive outcomes as required by years three and five. If the grants had been awarded competitively at the outset, for the full five years of the program's initial authorization, the states that were awarded grants would have been able to plan and scale up their programs. It is the annual competition that creates unpredictable funding and difficult planning.

Beyond questions of logistics, the competitive structure proposed in Section 7 also raises equity concerns. First, all grantees are held to the same requirements and are accountable for improving outcomes for children and families in the benchmark areas specified in the legislation. In the first year,

because the funding is made available through a formula grant, all grantees receive a proportionally equitable amount of funding. However, if a competitive process is layered atop the formula grants in the remaining years of the program, grantees will still all be held accountable in the same manner but the proportionate amount of funding grantees receive will differ. There is no requirement that obligates states receiving additional funds to achieve additional outcomes or to make more progress towards benchmarks. In other words, some states will receive proportionally more federal funds to produce the same outcomes as states receiving proportionally less funding.

CLASP recommends retaining the formula grant structure for the full five years of the program's authorization, with the option of considering competitive funding once the program is reauthorized.

3. If a competitive grant component is retained, funding awards should be based on criteria related to the quality of implementation and progress toward outcomes, rather than on the model or models selected by the state.

As noted in the previous section, CLASP opposes changing the funding of the program from a formula grant to a formula grant with a competitive grant component. However, if such a structure is utilized, we urge that HRSA/ACF rethink the selection criteria suggested in Section 7. In Section 7 the criteria propose to allocate a portion of the funding beginning in year two of the program, at least in part, on the strength and quality of the studies of the models states choose to operate. We have a number of concerns with this approach. It appears that this would include making a distinction between RCTs and QEDs as outlined in Section 3.1. As noted in section one of our comments, we think ranking the studies as "high" "moderate" and "low" is inconsistent with the authorizing legislation. It is particularly problematic to tie those rankings to future funding levels. We worry that such an approach would have the practical effect of limiting all additional funding in the out-years only to models with evidence of effectiveness from RCTs.

In addition, if there is to be a competitive aspect to funding after the first year, it makes little sense to award funding on the basis of whether or not the state chose to operate favored model(s). Instead, if HRSA/ACF feel compelled to award the increased funds in the out-years on a competitive basis, then they should base such funding on actual performance under the new program and not on model selection. For example, the legislation requires that states demonstrate improvements in at least four of six benchmark areas after three years. HRSA/ACF might consider attainment of, or progress towards, these benchmarks in a competitive structure. However, as suggested by the structure of the program in the legislation and what is known about the realities of implementing and scaling up programs, it is unlikely that these kinds of outcomes will be available or reliable before at least three years.

CLASP recommends that funding continue to be formula based for the first five years of the program. If a competitive component is retained, however, funding decisions should be based on actual performance under the new program which can happen only after the states report on their benchmarks at the end of the third year.

4. Provide a description of the process to be used when states want to make the case that additional models beyond those named in the Mathematica report meet the criteria for "evidence-based".

We are pleased that in section 2.2 HRSA/ACF creates a process that allows states to offer additional information in response to the Mathematica report. This is essential to ensuring that the process for establishing the criteria for evidence of effectiveness is transparent. However, we think HRSA/ACF needs to provide additional guidance about how that process will work. For example, if a state wishes to operate a program utilizing just one model that it believes to be evidence-based but that model is not named in the Mathematica report, what will the process be for making the case that the model is evidence-based? How long will the review process take? Who at the Department of Health and Human Services (HHS) will ultimately make the decision regarding whether or not a model is evidence-based? How will Mathematica be involved in informing that final decision? If the evidence is reviewed and the model is determined not to be "evidence-based," will the state have an opportunity to revise its plan to include another model or models or will the state lose its funding for that year? We assume that a state could argue that a model not listed by Mathematica is "evidence-based" whether that model was screened out before detailed review or the model was reviewed but found by Mathematica to fall short of the "evidence-based" criteria. However, it would be useful for HRSA/ACF to clarify that states may raise questions about Mathematica's conclusions in either case.

CLASP recommends better outlining the process for states to demonstrate that unlisted models meet the criteria of "evidence-based" so that the decision-making process is appropriately transparent. Additionally, CLASP recommends that the final criteria make clear what process HHS will use beyond FY 2011 to obtain and review new research and determine whether additional models are "evidence-based."

5. Provide states clearer guidance about what information will be required in order to receive funding for "promising approaches."

Up to this point HHS has not provided guidance on what information is needed regarding "promising approaches" for states that wish to operate such programs as part of their broader home visiting system. Without clear guidance regarding these approaches, it will be a challenge for states to develop plans that take advantage of the opportunity to use up to 25 percent of their grant funds for "promising approaches" and innovation may be stymied.

CLASP believes states wishing to operate a "promising approach" as part of their home visiting program should articulate, in their state plan, what model(s) will be used and a rationale indicating why the state considers the model(s) to be a "promising approach." This rationale should include any available program data, studies or other such documentation of the model's performance.

We do not think that there should be a formal process within HHS for verifying that these models are "promising". Instead states should be encouraged to implement approaches that they believe have

shown promise in achieving positive outcomes in the required benchmark areas for children and families. States using these promising approaches will be held to the same standards as other states in terms of achieving outcomes in the benchmark areas.

6. Provide a list of models selected for the Mathematica study immediately.

In order to prepare to revise their state plans in response to the final criteria for evidence of effectiveness, states need to know which models were selected for Mathematica's study as soon as possible. For some states the results of the study will not impact their plans but for others revisions may be important. For example, states may need to rethink which models will be operated as "promising approaches" or gather relevant information on a model that is not included in the Mathematica review but which the state believes to be "evidence-based."

CLASP urges HRSA/ACF to provide a list of the models selected for Mathematica's study immediately. Additionally, it is essential that the list of models determined to be "evidence-based" be released as soon as it is available, so states can respond to the review and analysis, by adjusting their plans or preparing additional materials and evidence about models that may not have been included or selected in Mathematica's study.

CLASP appreciates your consideration of our comments and would be happy to meet with you to discuss them in further detail. We believe our recommendations will strengthen the final criteria so they better reflect the law's goal of helping states build the capacity to implement a coordinated system of early childhood home visitation. We also believe our recommendations will strengthen the final criteria by providing much needed information, particularly as related to process, so that states are well-prepared to update their state plans and dialogue with HRSA/ACF as appropriate. We look forward to opportunities to work together on this exciting program and others designed to improve outcomes for children and families.

Sincerely,

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