LeadingAge Wisconsin
Better Services for Better Aging

September 13, 2021

To: Otis Woods, DQA Administrator
From: John Sauer, Robin Wolzenburg and Brent Rapos, LeadingAge Wisconsin

Subject: Regulatory Reform Ideas and Observations

As we discussed, the following provides a snapshot of ideas to improve the nursing home regulatory system. We would be happy to provide more details on each of the offered suggestions; the intent of this communication is to provide you with a **working list of ways to positively change the nursing home regulatory system** so that our conversations have a starting point for discussions with DHS representatives and other officials interested in improving the current system:

Regulatory Reform Ideas for Consideration

- Seek a federal **nursing home survey pilot** to allow abbreviated surveys for high performing facilities. Qualifying facilities could be surveyed every 3rd year. Inside the 3-year period, high performing facilities could be subject to random validation surveys that would target a small subset of the higher performers. This would free up additional survey resources to aid lower performing facilities. {For your information, I am also attaching the documents from the Wisconsin Nursing Home Pilot Proposal that was jointly developed nearly twenty years ago by representatives from DHS/DQA, the advocates and the provider associations. Most LTC observers would agree the need for regulatory reform is even more important today than in 2002.}

- Ensure that some type of **surveyor Trauma Informed Care education** (DQA staff orientation and ongoing in-service training) has been implemented so that surveyors have sensitivity (empathy) training related to what providers, staff, and residents have experienced, particularly during this pandemic. We look forward to our continued discussions on how this education/training can positively impact DQA-Provider relationships and suggest it is time to update the DQA Shared Expectations Document: **www.dhs.wisconsin.gov/publications/p0/p00098.pdf**

- **NHSN reporting**
  - Switch frequency to monthly rather than weekly. Switch reporting positive tests from within 24 hours to weekly.
  - Do not require NHSN reporting to be tied to APU compliance.
  - Remove some unnecessary data elements to ease reporting burden. For example, keep the general employee category rather than having the facility categorize by type of employee in facility. This new reporting change is happening soon which

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will result in an unnecessary burden during the weekly reporting process. The focus of most long-term care organizations at this time is trying to manage the COVID surge in their communities.
    - Reminders for missed reporting before cites are issued (3 day-grace period).

- **CNA certification lapse-time** extended/disregarded. Delete provision requiring a person to work at least 8 Hours in 24-month period to retain CNA recertification.

- **CNA training program prohibition**. Impose only in instances where the deficient practice impacts training or quality of student's education in the program.

- Revisit efficacy/necessity of **CNA train-the-trainer programs** (retain RN requirement).

- **Delete Heightened Scrutiny** requirements for facilities that serve older adults. Allow shared staff and common space/programming and activities to aid in Medicaid member life enrichment. Do not force isolation on a campus-based setting.

- Investigate the **pass/fail rates of CNA programs** to assess individual program efficacy.
    - Allow test takers additional time beyond the 120 days if they fail a test. Allow for some level of test retakes without retaking the course.

- Including providers or **provider representatives in grid calls** so survey leadership receives both sides of the story.

- **Suspend the use of CMPs as an enforcement mechanism**, except in the most egregious cases. Instead, and when appropriate, enforce the direction of dollars into quality improvement remediation plans.

- **Revisit IJ determination as "potential for harm".** The word "potential" leaves a lot of room for surveyor interpretation and has led to varying levels of enforcement among different survey teams.

- Allow appropriately **trained or experienced non-CNA staff** (e.g., dietary or activity aides) to assist CNAs with certain resident assistance duties. Expand acceptable tasks on the **Noncertified Individuals in Delivery of Non-Hands-On Services** guide.

- **Suspend One-star rating for missed/late PBJ submission**: Allow a grace period for late submission. Another potential solution would be the dropping of only one-star from the prior quarter (moving from a five-star to a four-star), with a one-star rating given after two consecutive quarters of missed data. Many good facilities get hit with a one-star rating mostly due to turnover and a missed submission and the only time that is discovered is when new 5-star ratings are issued when it is too late. This impacts referrals and rates paid to facilities by insurance companies.

- Consider eliminating the **bell curve for the CMS Five-Star Rating System** and equally weighting the Five-Star survey, quality, and staffing components to focus on quality improvements.

- Extend **temporary and emergency aide programs** indefinitely.

- Reinstate **MDS late submission blanket waiver**.

- **Revisit mechanical lift age requirements** (16-year-olds).

- **Prohibit Medicare Advantage plans from requiring significant duplicative documentation** for Section GG, such as narrative notes summarizing the resident's function for every item in section GG for nine shifts. This requirement is time-consuming, duplicative, and above and beyond CMS's Medicare A requirements. Require Medicare Advantage plans to follow CMS Medicare A documentation guidelines.

- Allow **DON hours** (and other managers that are CNAs or have completed the emergency/temporary nurse aide training) spent working as direct caregivers to count towards staffing hours to recognize the reality of the workforce crisis.

- **Reevaluate concurrent or "look-behind" federal survey process** that have resulted in increased violations.

Thank you for the opportunity to offer our regulatory reform suggestions. We look forward to discussing these proposals with you and other DHS officials in the near future. Should you need more information on these ideas prior to our meeting, please do not hesitate to contact us.

We remain hopeful that we are on the path towards a better LTC regulatory system.

For Your Information: Over the years, we've collected various reports on the need for regulatory reform. As you ponder the above offered suggestions, the following articles directly call for system reforms that improve nursing home quality *and* protect vulnerable older adults and persons with a disability:

- **AMDA Survey Taskforce to Facilitate Rethinking of an Upgraded Survey Process.** LTC task force pushes for 'complete redesign' of nursing home survey process that places less blame on providers**: https://www.mcknights.com/news/ltc-task-force-pushes-for-complete-redesign-of-nursing-home-survey-process-that-places-less-blame-on-providers/**

  The survey process for nursing homes should focus on engaging geriatric experts more and recognizing high-performing and innovative facilities rather than assigning blame and focusing on punishments for providers, according to a long-term care task force.

"Current survey processes continue to fly in the face of proven principles of internal motivation for promoting performance, instead assigning individual blame, focusing on punishments, and impinging on provider autonomy. It is important that we take a fresh look at the approach and value of the survey process and how it should be improved," stated the AMDA Survey Taskforce to Facilitate Rethinking of an Upgraded Survey Process.

The group includes geriatrician Michael Wasserman, M.D., AMDA president-elect Karl Steinberg, M.D., past AMDA president Arif Nazir, M.D., Alan Horowitz, Esq., RN, and James Lett II, M.D. Its comments were made in **an editorial published in the current issue of *JAMDA*.** The task force was facilitated by AMDA — The Society for Post-Acute and Long-term Care Medicine after noting the intense scrutiny faced by Life Care Center of Kirkland, the first nursing home to suffer a widespread coronavirus outbreak in the U.S.

The facility, which had a five-star rating, **received three Immediate Jeopardy deficiencies** for its pandemic failures. The experts questioned the accountability measures placed on the highly-rated facility during such an unprecedented emergency. {Note see 60 Minutes segment on this issue: **https://www.youtube.com/watch?v=fPqHCcvP_cA**).

"Should accountability necessarily equate to punishment, and how often does punishment translate into improved quality in the future? COVID-19 gives us a prime opportunity to pose these questions and develop a framework within which to respond to them," they said.

Compliance up, but not quality?
The group found that the survey process helps improve regulatory compliance but lacks in ensuring quality of care improvement. A lack of adequate funding and statewide variability also impacts the consistency of surveyors.

Additionally, it found that team morale is negatively impacted by the survey process, and over time the process has evolved to have a heightened focus on adversarial and punitive practices.
The experts called for the process to instead highlight high performers, incorporate constructive feedback and seek collaboration to help other providers improve. They also suggested engaging experts in geriatrics, like increasing medical directors' role in the quality assessments and problem solving, to assess nursing home performance.

"It is high time that push for a survey process that not only assess performance in a no-blame fashion but also facilitates person-centered care and innovations in care delivery, while continuing to fairly account for deficient practices and negligence. This may be a tall order, but [nursing home] residents and the staff who serve them deserve nothing less," the group concluded.

- **Medical Directors (Physicians) call for nursing home regulatory reform:**
  https://www.jamda.com/article/S1525-8610(20)30805-7/fulltext and
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7297162/

The Nursing Home Industry and Regulatory Process Need Massive Restructuring
Our nursing home infrastructure was built 50 years ago, and an initial set of reforms was passed by Congress and signed into law in 1987, designed to improve and standardize nursing home care in light of incidents of elder neglect and abuse that were truly horrifying.[5] After 30 years with no substantive changes, the nursing home regulatory framework was revised in October 2016.[6] But the model of care underlying this framework and the assumptions hidden within it are still woefully out of date.

Life expectancy in the United States in 1970 was age 70 years; today, people live well into their 90s and some 85% of all nursing home residents are over 75 years of age.[7] Most nursing home care

was considered "custodial" in the 1970s—long-term care that did not require skilled nursing—and the standardization of skilled nursing facilities did not take place until 1972.[8] Today, most nursing home and assisted living residents have multiple comorbid conditions, and roughly 70% are living with some form of cognitive deficit,[9] including 48% with dementia.[10] Close attention and management of complex drug regimens that often include 10 or 15 different medications is routine.[11] This is a very different patient population from the previous generation.

Some nursing homes are specialized to provide hospital-level care such as ventilator therapy, cardiac rehabilitation, or joint replacement rehabilitation, but the large majority of our 15,400 nursing homes look very much like they did 30 years ago—just with a very different resident population. Staffing levels have stayed fixed, while residents' needs and medical complexity have increased well beyond this minimal capacity. The buildings themselves are older, with smaller rooms, often 2 to 4 individuals to a room, narrow hallways, and old heating, ventilation, and air conditioning systems. Even when some nursing home organizations have made the investment to renovate their buildings or build new nursing homes with more home-like "neighborhoods," they must often get past regulatory restrictions that have not kept up with the times.

Unfortunately, the nursing home inspection process—whose intent when Congress passed the Nursing Home Reform Act of 1987 (OBRA) statute was to be a corrective framework to guide nursing homes to implement best practices—has now become punitive. Fines intended as incentives to implement better care are now often weaponized by the CMS, politicians, and survey teams whose inspection processes are more damaging than helpful. And in the era of COVID-19, punitive surveys are not only demoralizing and unhelpful, they are causing nursing home organizations to cut programs or even to consider closing facilities.[12, 13, 14] And recent research[15] suggests little connection between the CMS quality measures such as a nursing home's star rating or prior infection control deficiencies, and the incidence of COVID-19.

- **National Academies of Sciences, Engineering, and Medicine** is looking into how this country regulates nursing homes: (The National Academies of Sciences, Engineering, and Medicine are private, nonprofit institutions that provide expert advice on some of the most pressing challenges facing the nation and world. Our work helps shape sound policies, inform public opinion, and advance the pursuit of science, engineering, and medicine.) **https://www.nationalacademies.org/our-work/the-quality-of-care-in-nursing-homes**

  An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will examine how our nation delivers, finances, regulates, and measures the quality of nursing home care with particular emphasis on challenges that have arisen in light of the COVID-19 pandemic. The committee will consider a broad range of issues such as:

  - ways to generate and assess the evidence base for interventions, structures, policies, and care models to promote care innovation while assuring quality of care;
  - the impact of current oversight and regulatory structures (including enforcement and penalties) on care quality and outcomes, which may include examination of: the meaningfulness of the current five star rating system and how it is interpreted by consumers and clinicians; and /or the validity, efficiency, and effectiveness of the current survey and certification structures and methods, including inspection standards, training of surveyors, and their adherence to standards.

- **Health Affairs Article** from 20 years ago calling for Nursing Home Regulatory Reform: **https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.20.6.128?journalCode=hlthaff**

State of Wisconsin
Department of Health and Family Services

Scott McCallum, Governor
Phyllis J. Dubé, Secretary

April 4, 2002

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Dear Secretary Thompson:

The State of Wisconsin requests authorization to pilot a modified nursing home survey process. We are making this request pursuant to section 1115 of Public Law 92-603. This law provides broad authority to the Secretary of Health and Human Services to allow for demonstrations, experiments, and pilot projects in efforts to resolve major health care financing issues and to develop innovative methods for the administration of Medicare and Medicaid. The current survey process limits states' ability to allocate necessary resources to nursing homes experiencing significant problems. Our proposal allows Wisconsin the flexibility needed to improve the quality of care and quality of life for vulnerable nursing home residents to a greater extent than we are presently able to do.

Wisconsin's pilot proposal has been developed collaboratively among the Wisconsin Department of Health and Family Services, nursing home representatives, and resident advocates. It uses the entire framework of the existing nursing home survey process, as required by the Centers for Medicare and Medicaid Services, but tailors the length and depth of the survey to the individual facility. Some facilities will experience no change in the current survey process. Others will experience either directed or a more intensive survey, depending upon the facility's history and the problems that are identified during the initial phase of the survey. This proposal does not change the frequency of nursing home surveys, all Wisconsin nursing homes continue to be surveyed annually.

Our proposal retains the focus upon quality of care, quality of life, and resident rights. At the same time, it offers flexibility to the state survey agency, allowing it to target limited state survey agency staff for facilities experiencing more significant problems than their peers. It will also allow the survey agency to assist noncompliant facilities to come into compliance, ultimately improving quality of care and quality of life, through the provision of limited technical assistance and the sharing of "best practice" guidelines.

Wisconsin will continue to survey for recertification all nursing homes within the present 9-15 month interval, maintaining a 12-month average as required by federal law. Each survey, at a minimum, will include the required elements outlined in Title XVIII of the Social Security Act, section 1819(g)(2)(a)(ii). Specifically, each survey will include a case-mix stratified sample of residents that evaluates:

- the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary, and nutrition services, activities and social participation and sanitation, infection control and the physical environment;

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- written plans of care and an audit or resident assessments to determine the accuracy and adequacy of each; and
- residents' rights.

Our survey proposal will not modify or limit current regulations relating to federal enforcement actions. It will be used within the structure of the current survey process.

We propose piloting this survey process in the western region of the state, which encompasses approximately 90 nursing homes, or 21% of the certified nursing homes in Wisconsin. The pilot will continue for three years. We will evaluate the effectiveness of the pilot through a research team consisting of faculty and students from the University of Wisconsin (Eau Claire and Madison) and the University of Minnesota. Details concerning this evaluation are included in the final four pages of the attached proposal.

Thank you for reviewing our proposal. If you have additional questions, please contact Susan Schroeder, Director, Bureau of Quality Assurance/Department of Health and Family Services, at 608-267-7185. Wisconsin is ready and willing to work with the Department of Health and Human Services and the Centers for Medicare and Medicaid Services to improve the nursing home survey and certification process.

Sincerely,

Phyllis J. Dubé, Secretary
Department of Health and Social Services

George Potaracke, Executive Director
Wisconsin Board on Aging and Long Term Care

Susan Schroeder, Director
Bureau of Quality Assurance

John Sauer, Executive Director
Wisconsin Association of Homes and Services for the Aging

Tom Moore, Executive Director
Wisconsin Health Care Association

Proposal to Pilot an Improved Long Term Care Survey Process Submitted by the State of Wisconsin

Introduction

Providing and insuring that quality care is being offered to residents of nursing homes continues to be a challenge in our society (Dept. of Health and Human Services Nursing Home Quality report, 1999 and past Institute of Medicine reports, 1983, 1986). There has been a lot of progress in redefining the best interests and needs of the consumers over the years (e.g. OBRA, MDS initiatives, and recent QOL activity), although the current federal system does not afford states sufficient flexibility to explore more effective ways of assessing and measuring the extent to which changing consumer needs and federal standards are being met. Advocates are also very concerned about the process of insuring quality standards are being met and have expressed support for modifications to the existing process (Various current National Citizens' Coalition for Nursing Home Reform and AARP publications and policy statements). On the provider front, frustration with the process has continued to grow (e.g. Bad Medicine report, New York Association of Homes and Services for the Aged, 2001), although a willingness to explore new options has only recently seen any significant energy (Pioneers Network Proceedings, 1997, 2000 and the Wellspring evaluation study conducted by the Institute for the Future of Aging Services, 2001). Lastly, agencies charged with the regulatory duty to monitor the quality of care and services delivered have also begun to express interest in exploring approaches for incremental positive change.

On January 8, 2001, a meeting coordinated by nursing home provider organizations of the six Region V states was convened in Chicago, Illinois, to discuss a regional approach to piloting a revised long term care survey process. All six Region V State survey agency directors

were present and support improving the long term care survey process.

It was agreed the current survey and enforcement process is valuable. However, revisions are necessary to improve the effectiveness and efficiency of the process, to best utilize limited resources, and to encourage providers to continuously seek excellence.

Purpose

With that background in mind, Wisconsin representatives (regulators, providers and advocates) collectively support the development of a revised long term care survey process and request that this reformed process be piloted within Wisconsin and ultimately with the other Region V states.

The supported goals of the revised long term care survey process are:

Primary Goals

1. The revised survey must focus on quality of care, quality of life and resident rights to ensure the welfare of each resident.
2. The survey and enforcement system must better target chronically poor performing providers.
3. The system must distinguish facilities that provide exemplary care and embrace an effective quality assurance process.
4. The revised survey process shall use regulatory resources more effectively and efficiently to target and address problem areas, taking account of budget considerations.
5. When appropriate, during the course of the survey, surveyors may provide referrals for technical assistance designed to communicate provider best practices to improve quality of life and quality of care for residents.

Assurances

1. All homes will continue to be monitored within a 9-15 month schedule during the duration of the pilot program.
2. The survey process will not modify the current federal certification requirements relating to nursing facilities.
3. The survey process will not modify or limit the current provisions relating to adverse actions.
4. The survey pilot will be instead of, rather than in conjunction with the standard, federal survey.
5. The new pilot survey process will not replace BQA responsibility for Life Safety Code issues.

Under the pilot survey process, regulators will assign facilities into one of three categories. These categories will determine the scope and intensity of the individual facility's survey. The three categories are: 1.Intensive; 2. Standard; and 3. Directed. The manner in which facilities are assigned to these survey categories will be determined by a comprehensive pre-survey analysis and the initial findings during the on-site survey visit.

Pre-survey Decision Making

In assigning facilities to a survey category, regulators will use a variety of data, documents, facility characteristics and indicators. Examples are:

a. Survey compliance history (post IDR);
b. Complaint history (substantiated and other);
c. Information from the Ombudsman and other advocates;
d. Quality indicators (QIs) and MDS data;
e. Information on change of ownership, administrator, and DON;
f. Resident census and roster information;
g. Staffing information;
h. Preadmission screening/annual resident review (PASARR);

i. Regional office file review;
j. Annual medical assistance nursing home cost report;
k. Known quality assurance and improvement efforts undertaken by the facility;
l. New facility and/or organization methods or tools developed to assess quality of care and services.

As part of this pilot proposal a panel of experts will be assembled to evaluate the relative importance and influence of this pre-survey information. This panel will represent the diverse perspectives of the field, including representatives from consumer advocate groups, provider organizations, regulatory agencies and outside experts in the quality management field. Each expert will be asked individually to rate the influence of each of these categories of information when predicting a good or bad survey. The group will then be brought together and use a nominal group process to develop an initial model for decision-making.

This review, in turn, determines the following aspects of the survey:

a. Time allotted for the survey;
b. Composition of the survey team;
c. Areas of care that warrant special attention during the survey; and,
d. Identification of residents or types of residents who are good candidates for potential inclusion in the sample.

All pre-survey decisions on category of survey are tentative for scheduling and operational purposes. Once on-site, the survey is "fluid," in the sense that following the first day of survey activity (or sooner if less time is needed) the original decision about category of survey, care area emphasis, or team composition is confirmed or modified on the basis of what the surveyors find in the facility.

Through this pre-survey review process a survey category is chosen. The categories are:

1. Intensive – current survey supplemented by more and/or specialized surveyors
2. Standard – same as current survey
3. Directed –reduced sample size and focused review.

Compared to the Standard survey, an Intensive survey will be assigned greater survey resources, whereas the Directed survey will require less surveyer time and presence in the facility.

If any of the following criteria are met, the facility will <u>not</u> be considered in the pre-survey decision making as a candidate for a directed survey:

1. Immediate jeopardy (IJ) finding within the last survey cycle;
2. Substandard quality of care finding within the last survey cycle;
3. Had instances of either IJ or substandard quality of care within two of the last four survey cycles.
4. Have had imposed a civil monetary penalty or a denial of payment for new admissions within the last survey cycle;
5. A facility where a temporary manager has been imposed within the past two survey cycles.

<u>Intensive Survey</u>

Facilities assigned to this category will receive heightened regulatory scrutiny and ongoing attention. These facilities are those identified as having serious quality of care/life compliance concerns during the pre-survey process. The intensive survey is generally the same as the "standard" survey process presently used, but with an additional six hours or more scheduled to allow for a more in-depth review of

potential concerns. Facilities assigned to intensive surveys may also be subject to compliance surveys prior to or subsequent to the intensive survey.

Standard Survey

The standard survey will generally reflect the current federal certification survey process including the current sample sizes and tasks.

Directed Survey

The directed survey will be reserved for those facilities with ongoing exemplary performance. The directed survey will be used when the pre-survey decision making and initial onsite review verifies the facility's exemplary performance. The sample size will be smaller than for a standard survey and will be determined by the size of the facility and a review of the facility's quality indicators.

The directed survey will focus on current residents, although closed record reviews will be conducted if identified as a concern. The directed survey will focus on the key areas that have been proven to have a large impact on the quality of care and life for residents. Specific federal codes requirements can be found in the Resident Behavior and Facility Practice s.483.12, Quality of Care s.483.15 and Quality of Life 483.25 regulations. The oversight group will consider new survey methods or tools developed to assess the quality of care and services for use within the pilot study. These areas will be shared with all provider participants in advance of the commencement of the study. As in the standard survey, the surveyors will be empowered to address any area, if during the course of the survey potential problems are detected. Environmental concerns will be pursued only if issues or concerns are identified during the initial onsite or as part of a selected resident review. The medication pass observation will no longer be mandatory, but can be conducted if indications warrant.

The record review will be based on resident/family interviews and surveyor observations.

Survey Category Assignment

A critical element of the pilot will be assigning facilities to the appropriate survey category. This assignment process will be developed and refined, consistent with the goals of the pilot program (see page 2) based on experience and facilities' performance and characteristics. The decision-making framework developed by the expert panel will be used as a primary resource by the survey teams participating in the pilot project. This fluid survey system will allow for the movement up or down the continuum of survey categories, based upon the surveyor's experience on-site, once the survey has begun. Therefore, if few or no problems are being detected, a less intensive survey may be completed (e.g., a standard survey becomes a directed survey). If more problems are detected than will have been predicted by the pre-survey activity, a more intensive survey is completed (e.g., a standard survey becomes an intensive survey).

This represents a more flexible approach that takes advantage of the professional decision making ability of our surveyors and regional offices.

Compliance Surveys

Another critical element of the proposed survey pilot is to supplement the annual survey with compliance surveys. The purpose of the compliance visit is to monitor specific providers between follow-up surveys and the next certification survey. The pilot program will aggressively target facilities that have a history of attaining compliance for the follow-up survey, but then regress to non-compliance. The frequency and scope of compliance surveys will be

flexible. Supervisors and the survey team select facilities for compliance visits.

Implementation Keys

The development of an effective implementation plan will need to take into account the following critical factors:

1. Initial and ongoing communication with all participating entities concerning the purpose and goals of the project.
2. Survey process refinement for the different types of surveys recommended for this project.
3. Training of all survey staff involved in the project.
4. Development and ongoing review of facility assignment protocols used for determining category of survey.
5. Identification of initial data collection needs, methods and tools, including both quantitative and qualitative information.
6. Development and maintenance of a system for the collection and referral of best practices.

The pilot project advisory committee will be responsible for reviewing and critiquing the initial implementation plan that is developed, and monitoring the progress of the project with the research team throughout the pilot project.

Evaluation Summary

The pilot program should be evaluated under the auspices of the Centers for Medicare and Medicaid Services (CMS) and other outside parties. The evaluation should assess whether the goals of the pilot have been met.

The evaluation component will utilize a combination of approaches and be guided by an advisory panel to insure that necessary adjustments to the evaluation plan are made throughout the pilot.

The primary questions the evaluation will be probing are the following:

1. Do the actual changes in the allocation of resources in the redefined survey process improve and/or maintain the quality of care in facilities?
2. How effective does the system target poor performing providers?
3. What is the relationship between the pre-survey decision making information and performance of facilities measured in terms of survey results?
4. What have been the resulting cost implications of these changes?
5. Have providers used outside resources more often to assist in implementing changes to improve their service delivery?
6. What other unanticipated improvements to the survey process have been identified during this pilot project?

The above questions will provide preliminary guidance to help frame the specific implementation and evaluation approach, which will be described in detail for each of these questions in a full proposal.

In general, this evaluation will use pretest-posttest measures to assess the above questions and the nature of this design is non-experimental. The evaluation approach will use both quantitative and qualitative information to help assess the success of the pilot. Initial information that will be used includes the pre-pilot provider characteristics information and past history of survey performance of all the providers in the defined pilot region. This baseline information will be extremely useful when the evaluation team is assessing any changes and their correlation to other variables.

An assessment of perceptions prior to the pilot will be done with providers, and regulators. A sample of perceptions, gathered with the use of structured interviews, will also be done during the pilot period to help insure that any adjustments to the pilot could be made before the end of the study period. This sampling will reflect the three groups of assigned survey intensity levels. A posttest assessment of perceptions will be done with all the participating providers and

regulators at the end of the pilot period. The evaluation will conclude with a thorough assessment of any changes that resulted during the pilot period, using much of the pre-survey characteristics information, actual survey findings, reported activity changes and other outcome data gathered on an ongoing basis. A full report will be issued pending the review of the pilot study advisory committee, which would include any cause and significance findings or inferences drawn from changes experienced during the study.

The time period for this study is 36 months, which would allow for a baseline survey and two successive surveys at the majority of facilities involved in this pilot project.

The Pilot Project Advisory committee will consist of representatives from the research evaluation team, participating regulatory agencies, provider representatives from the pilot region, a provider association member, a resident advocacy agency and outside experts in the quality improvement field.

Location

This proposal recommends using the entire Western region of Wisconsin to participate in this pilot project. This identified region is comprised of 19 counties, approximately 90 facilities, and uses primarily two survey teams.

Staffing

The primary evaluation and project team would include Doug Olson, the Principal Investigator and Mary Zwygart-Stauffacher, as Co-PI, both from the University of Wisconsin - Eau Claire. These two faculty members have extensive experience in long-term care, and represent an administrative and nursing background. The team would also include expertise and senior research support requested from David Zimmerman from the University of Wisconsin – Madison and Robert Kane and Sandra Potthoff both from the University of Minnesota. A regulatory consultant with extensive government

experience would be retained by the project. Coordinators and staff for the evaluation and best practice components of the pilot study would be hired for the duration of the project.

Budget Estimate

The proposal contains a two-pronged approach to achieving the goals outlined for this project. The primary focus will be on the effective implementation of this new alternative survey process with all of the participating entities, including regulators, providers and consumers. The evaluation component of this study will also be agreed upon at an early project stage to insure availability of measurable results to assist the researchers and Advisory committee draw conclusions about the success of this pilot.

A second element of this project is the establishment of a "best practices" collection and dissemination unit or system for the participating providers and regulators to use as a resource during the pilot project. These activities would be administered by the Center for Health and Aging Services Excellence at UW-Eau Claire and work in consultation and collaboration with identified resources and/or any State of Wisconsin initiative. This effort would help serve as a model for a broader program implemented on a statewide basis.

Funding for this project would be secured from a variety of sources, although it is the understanding of the planning group that the majority of resources would be requested from an external foundation source. The preliminary budget for this project would include funds for the following:

A. Primary Project Implementation and Evaluation Funds

Personnel:	**% of FTE**	**Year 1**	**Year 2**	**Year 3**
Principal Investigator				
Dr. Douglas Olson				
Academic Year	.20	$10,099	$10,604	$11,134
Summer Session	1.0	$11,220	$11,781	$12,270

Co-Principal Investigator				
Dr. Mary Zwygart-Stauffacher				
Academic Year	.10	$ 6,362	$ 6,680	$ 7,014
Summer Session	.50	$ 7,068	$ 7,422	$ 7,793
Project Coordinator	1.0	$50,000	$52,500	$55,125
Data Analyst	.75	$36,000	$37,800	$39,690
(2) Graduate Research Assistants	2.0	$28,000	$29,400	$30,870
Fringe Benefits:				
PI (35%)		$ 7,462	$ 7,835	$ 8,226
CO-PI (35%)		$ 4,701	$ 4,936	$ 5,183
Project Coordinator (35%)		$17,500	$18,375	$19,294
Data Analyst (35%)		$12,600	$13,230	$13,892
Graduate Assist. (20%)		$ 6,000	$ 6,000	$ 6,000
Supplies:				
Training for staff		$10,000	$ 5,000	$ 5,000
General Office Supplies		$ 5,000	$ 5,000	$ 5,000
Meeting Expenes		$10,000	$10,000	$10,000
Dissemination Expenses		$ 5,000	$ 5,000	$ 5,000
Other:				
(3) Faculty Consultants		$18,000	$18,000	$18,000
Regulatory Consultants		$10,000	$ 5,000	$ 5,000
Travel:		$15,000	$15,000	$15,000
Total Direct Cost		$270,012	$269,563	$279,491
Total Indirect Direct Cost (42%)		$ 82,745	$ 86,757	$ 90,926
Total Project Cost		$352,757	$356,320	$370,417

B. Project Best Practice and Technical Assistance Funds

Personnel:	**% of FTE**	**Year 1**	**Year 2**	**Year 3**
Best Practice Coordinator	1.0	$37,000	$38,850	$40,793
Web Site Developer	.5	$15,000	$15,750	$16,538
Fringe Benefits:				
Coordinator (35%)		$12,950	$13,598	$14,278
Web Developer (35%)		$ 5,250	$ 5,513	$ 5,789
Supplies:				
Technology Cost		$ 5,000	$ 5,000	$ 5,000
Total Direct Cost		$ 75,200	$ 78,711	$ 82,698
Total Indirect Direct Cost (8%)		$ 6,016	$ 6,297	$ 6,616
Total Project Cost		$ 81,216	$ 85,008	$ 89,314
Total Overall Direct Costs		$345,212	$348,274	$362,189
Total Overall Indirect Costs		$ 88,761	$ 93,054	$ 97,542
Total Overall Project Costs		$433,973	$441,328	$459,731

These estimated expenses would be incurred during the project. The budget would be refined based on further justification outlined in more detail with a detailed plan of activities, and the agreement on the scope of responsibilities required for project implementation, research and evaluation activities, and the successful attainment of a best practices model.

* These are estimates that would be adjusted based on the guidelines and protocols of participating funding sources.

Dissemination

The research team and pilot sponsorship groups would be committed to sharing information on a semi-annual basis regarding progress and any preliminary findings of the project. Further, it is anticipated the results of this project would serve as one of the significant elements of a broader effort to revise and improve the current long-term care survey process in this country.

The Secretary of the Department of Health and Human Services (HHS) would be authorized to waive certain requirements of the nursing home survey and certification process in order to test and implement innovative alternatives to the survey process. The language could be patterned after Section 2(c)(1) and (2), "Promoting Innovation and Quality Improvement Through State Waivers," of H.R. 3437, the "Medicare and Medicaid Nursing Facility Quality Improvement Act of 2005" introduced in the 1st Session of the 109th Congress;

Survey Pilots: Under H.R. 3437, the "Medicare and Medicaid Nursing Facility Quality Improvement Act of 2005", the HHS Secretary was given waiver demonstration authority to promote innovation and quality improvement in the nursing home survey and certification process. The bill reads: "At the request of a State, but not to exceed a total of 3 States, the Secretary may waive provisions of this subsection relating to survey and certification procedures in order to test and implement innovative alternatives to the survey process otherwise applicable. The Secretary shall provide special consideration to the application of alternative procedures that increase the use of outcome measures, the incorporation of quality of life procedures, and improve consistency and accuracy in deficiency determinations and survey results. The Secretary shall approve a waiver request if applicant demonstrates significant potential for improving the quality of care, quality of life, and safety of residents. The Secretary shall only consider waiver applications under this paragraph from a State under this paragraph if the State has convened and consulted with appropriate stakeholders in the State, including representatives of nursing facilities, consumers groups, the State long-term care ombudsman, labor organizations (and where such organizations are not present in the industry, other employee representatives), and licensed health care providers, to assist in developing their alternative system. In determining whether to grant such waivers, the Secretary shall take into consideration the views of the stakeholders convened by the State."

The Quality of Care in Nursing Homes in the 21st Century

In 1986, the Institute of Medicine (IOM, now the National Academy of Medicine) completed an evidence-based examination of nursing home quality and issued the landmark report *Improving the Quality of Care in Nursing Homes.* Soon after, Congress enacted the Nursing Home Reform Act as part of the Omnibus Reconciliation Act of 1987 (OBRA 87), after which the Health Care Finance Administration (now CMS) issued comprehensive regulations and survey processes to "ensure that residents of nursing homes receive quality care that will result in their highest practicable physical, mental, and social well-being."

Over the 34 years since the IOM study, CMS has

- created the five star system,
- issued countless guidance documents and additions to the State Operations Manual,
- established requirements for Payroll Based Journaling,
- issued and revised life safety and emergency prep rules,
- changed the survey process, and
- issued additional regulations and requirements for participation in Medicare and Medicaid.

The original 1988 Conditions of Participation (the overarching regulatory structure for nursing homes) were reissued as Requirements of Participation in 2016, although there was no comprehensive review of the evidence to assure that they had in fact produced the desired outcomes.

Today, the U.S. spends over $170 billion on nursing home care annually, with extensive regulatory oversight. On March 6, 2019, the Senate Finance Committee held a hearing, "Not Forgotten: Protecting Americans from Abuse and Neglect." David Grabowski, professor of health care policy at Harvard Medical School, told the Committee at that hearing "in spite of [regulatory, financing, ownership] changes…" many quality issues identified in a 1974 Senate Aging Committee report persist today.

Changes in Health Care, Long Term Services and Supports, and Demographics

When the first set of standards implementing OBRA 87 was put in place, the contexts for policy, financing, program, research, and quality were very different. The ability to understand and measure quality in long-term care settings was in its infancy. Assisted living was nonexistent and continuing care retirement communities (life plan communities) were just getting started. Home and community-based services were newly developed features of long-term services and supports. Public funding for nursing homes was almost entirely via Medicaid. Health care was largely reimbursed via fee for service payments; there was no Medicare post-acute care and no Medicare Advantage program. The U.S. spent $40 billion on prescription drugs (compared to $344 billion in 2018). There were no electronic health records, personal computers were just coming on the market, and there was no internet.

In 1987 the average life expectancy in the US was 74. Today it is 79. Ten thousand Americans turn 65 every day. Half of today's 65 year olds will need some paid long-term care services before they die. By 2030, one in five Americans will be age 65 or older; the fastest growing group will be those over age 85. Marriage and fertility rates have declined, meaning that there will be fewer family caregivers available. Further, people living in nursing homes today have significantly more disabilities than the nursing home population of the 1980s. In 1985, many people in nursing homes did not require assistance with activities of daily living (ADLs), but today, more than 90% of nursing home residents need help (or cuing) with five ADLs and most have multiple chronic conditions.

Nursing Home Quality Today

Some practices that were harmful have been largely eliminated. For instance, 16% of facilities reported using physical restraints on residents as late as 1996; in the third quarter of 2018, although the quality measure specification has changed, less than 0.3% reported using physical restraints with long-stay residents. But this is a very narrow standard to judging quality. Research has identified many dimensions of quality that extend well beyond preventing harmful practices and the observed reductions in avoidable hospitalizations. The understanding of quality has advanced greatly and our ability to measure performance has improved. Furthermore, many innovations have occurred in the delivery of person-centered nursing home care, technology, professional practice, and the health care and long-term care environments.

Despite the three decades of experience and dramatic changes in these care environments, the fundamental approach to promoting quality in nursing homes has not been revisited. Neither the impacts of the regulatory framework created in 1987 nor how approaches to quality assurance might be modernized have been considered. As David Stevenson, associate professor of health policy at the Vanderbilt University School of Medicine, observed, there is a basic "tension concerning the performance and role of nursing home regulatory oversight." He points out that "advocates seem to have a 'more is better' view of nursing home oversight," while nursing home groups argue that "nursing homes are already one of the most highly regulated and penalized professions," and thus we have "reached a stalemate." He has suggested that "the recurring failures of the US nursing home regulatory system and quality of care over many years also beg the question of how we might do better…perhaps considering the limits of regulation or whether alternate strategies might yield better results."

Statement of Work:

Revisiting how our nation delivers, regulates, and measures the quality of nursing home care is a complex, but essential undertaking. An evaluation by the National Academies of Sciences, Engineering, and Medicine would likely need to address issues such as:

- current regulatory structures and how they link to care outcomes
- consistency of oversight, enforcement, and penalties (see graphic below on inconsistency of average fines)
- current nursing home payment models and whether they support delivery of high-quality care and regulatory compliance
- evidence about which interventions produce high quality care in nursing homes
- the effectiveness of the survey and certification structures and methods, including training of surveyors
- the workforce and competencies needed to deliver high-quality care in nursing homes, and the challenges in ensuring an adequate workforce in nursing homes and survey agencies
- what consumers and family members seek and value in nursing home care
- the meaningfulness of the five star system and whether consumers understand it
- alternative structures, policies, and care models to promote care innovation and assure quality