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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3260–P
P.O. Box 8010
Baltimore, MD 21244

Comments of Consumers Union –
Medicare and Medicaid Programs;
Reform of Requirements for Long-Term Care Facilities
CMS-2015-0083-0001

Consumers Union, the policy and advocacy arm of Consumer Reports, submits these comments in the above-referenced matter. We support the Department's proposed strengthening and clarification of the standards and protections for residents of nursing homes and other long-term care facilities, to better ensure safe, attentive, supportive, and effective care. And we also generally support the recommendations being submitted by AARP and others for further strengthening and clarifying those standards and protections. We offer comments on two aspects of the proposed rule, regarding (1) arbitration and (2) infection control and antibiotic stewardship, and medication oversight, in order to help the Department better achieve its important objectives.

Forced Arbitration

In section 483.70(n), the Department proposes to impose various conditions on nursing home residential contracts that require residents to give up legal rights and rely on arbitration to resolve as-yet-unknown legal disputes that may later arise. The Department also asks for comment on whether it should go further and prohibit such "forced arbitration" provisions in those contracts. As explained below, we strongly believe it should.

We share the Department's stated concern that, as we have noted in other contexts, forced arbitration deprives consumers of important legal protections, and undermines safety and quality

of service. In this regard, nursing home residents and their families are a particularly vulnerable population.

Although the conditions the Department would impose on forced arbitration are responsive to this concern we share with the Department, we do not believe these conditions can be effective in addressing those concerns and preventing the harmful impact of forced arbitration on nursing home residents. Instead, the more effective approach for appropriately protecting residents is to prohibit binding pre-dispute arbitration agreements in nursing home residential contracts altogether.

Arbitration was designed for far different circumstances. Historically, arbitration was conceived as an alternative mechanism for businesses to resolve contractual disputes between themselves. The businesses involved had comparable, if not equal, bargaining power, experience, and awareness of business risk. They had opportunity during negotiations to freely weigh the tradeoffs in jointly agreeing to forego their right to full consideration of their contractual dispute in a court of law, in exchange for what they might conclude could be reduced legal expenses or a speedier resolution. And they could negotiate the terms of the arbitration agreement to ensure that it appropriately protected the interests of both sides to the agreement. Under these circumstances, an agreement between the two businesses that any legal disputes later arising between them would be submitted to binding arbitration could accurately be said to have been entered into knowingly and voluntarily by both of them. Indeed, in this kind of situation, the two businesses might even decide to wait until a dispute actually arose, and then each consider if arbitration would be the preferred way to resolve it.

Unfortunately, the use of arbitration in contracts has been transplanted into an environment where none of these conditions is present, and is being increasingly used as a business strategy to coerce or trick consumers into relinquishing fundamental legal rights as a pre-condition for obtaining products and services. There is generally no comparability of bargaining position between the businesses forcing these arbitration clauses onto consumers and the consumers who are forced to accept them.

All too often, the consumers are not even aware that the arbitration clause is part of the form purchase agreement they are required to sign, a form presented as if a routine part of the sales interaction. Even when they are aware, they often do not realize the significance of the legal rights they are giving up. And even if they do have some sense of the significance, they generally have no choice but to sign anyway if they want the product or service.

As a result, consumers find themselves at the mercy of a procedure chosen by the business and tailored to its own convenience and interests. The proceeding and the result are generally kept confidential, so there is no public record to alert the public more widely to the problem, no matter how serious. There is no right of appeal, nor any requirement that the decision follow established law. The business chooses the arbitrator, who naturally comes to

regard the business with familiarity as a repeat patron, creating an inherent conflict of interest. The agreement often includes a prohibition against combining claims – which means that, when the legal costs of pursuing an individual claim exceed what can realistically be recovered, the individual claim is generally not brought, and the business escapes legal accountability entirely – even for a repeated pattern of wrongdoing. In these and other ways, arbitration agreed to pre-dispute takes place on the business's terms and is skewed in its favor.

Individuals being admitted into a nursing home facility, and their families, are particularly vulnerable. They are generally in urgent need of admittance, coming from acute hospitalization or another major adverse health event indicating that they need nursing home care for their health and safety, and that living at home or with family members is not a practical option.

These individuals are often elderly, and may not be fully capable of reading a legal document, much less asking the questions to fully understand its significance. Likewise, it is an emotional time for family members, who also have many logistical details to deal with. The emotional circumstances and urgency surrounding admission to a nursing home facility increase the risk that an arbitration agreement will not be fully understood by the resident or the resident's family or representative, and will not be entered into knowingly and voluntarily in any meaningful sense.

And once individuals are admitted, over time they can be vulnerable to a wide variety of acts of potentially severe neglect and abuse. Residents are utterly dependent on the facility maintaining and enforcing appropriate care and protection. The dangers of neglect and abuse include serious sores and infections, malnutrition, dehydration, asphyxiation, even sexual assault, among many others. The consequences can be painful, debilitating, dehumanizing, sometimes fatal. When the facility fails to meet its duty, it can take weeks or months before that failure, and the neglect and abuse, come to the family's attention. Removing the prospect of effective legal accountability increases those dangers, and leaves residents even more vulnerable and powerless.

The conditions being proposed by the Department reflect a recognition of these facts, and are a well-intentioned attempt to address them. But as well-intentioned as these proposed conditions may be, they will not overcome the basic shortcoming inherent in a before-the-fact agreement to arbitrate: that nursing home residents are, at a minimum, in the Department's words, "feeling coerced" into giving up important, fundamental legal rights, when their admission is urgent, and when they are in no position to meaningfully consider the consequences or assert their own interests.

For example, the proposed requirements that the binding arbitration agreement be explained to the resident being admitted, and that signing it not be a precondition for admittance, would all-too-predictably result in simply a separate one-page form addendum, stating in

contract boilerplate that the resident has had the arbitration agreement explained, fully understands it, and is signing it voluntarily. And this form would all-too-predictably be presented to the resident, without further actual explanation, in a stack of papers that the resident (or his or her representative) is asked by the friendly nursing home representative to sign as a routine but required part of the paperwork, as the resident and his or her family are rushing to finalize arrangements to be admitted.

We are all familiar with this kind of process in connection with the purchase of a home mortgage, a bank account, a car, and increasingly with the purchase of other every-day products and services. We are not expected to actually read the form, and if we should attempt to read it, and ask questions, the person asking us to sign often does not have answers other than "that's the standard form that everybody signs." This is an unacceptable process in any consumer transaction, but especially in a nursing home residential contract.

Efforts to ensure that the resident or representative actually reads the form, actually considers fully what it means, actually weighs the potential consequences in the event that various kinds of problems might arise, and truly voluntarily agrees in light of those considerations, are simply not going to be effective. The words on the form addendum will seem to ratify that all of that has occurred; the resident's or representative's signature will make it a foregone conclusion, precluding any objective assessment of whether it has in fact occurred.

The only effective way to ensure that an agreement by a nursing home resident to give up the fundamental legal right of access to the courts is truly a voluntary choice, made with full knowledge of the potential consequences, is to permit such agreements only after the problem has arisen, and the resident realizes that legal action is necessary. Even then, there remains a risk that a resident might be improperly induced to waive those legal rights. But at that point, the resident and family members will be far more likely to have both opportunity and cause to focus on and compare the pros and cons of arbitration and court action – and to be better aware of what dispute they are agreeing to remove from the judicial process established in the law for their protection.

Moreover, only if arbitration agreements are prohibited until after the problem has arisen, and when the consumer is making the agreement after an opportunity to carefully assess the benefits and drawbacks of arbitration as compared with court action, would incentives be in place for the facility to construct an arbitration process that is fair and effective on both sides. It is the all-important difference between persuading a well-informed consumer to choose an option, and imposing a requirement on a consumer through force or through sleight of hand. Unless the agreement is informed and voluntary, we are concerned that regulatory conditions will not be sufficient to capture and constrain the many ways in which the facility and its lawyers can tilt the process unfairly against nursing home residents and their families.

Finally, preserving legal accountability, and with the prospect of public exposure, fosters effective incentives for facilities to more broadly comply with their legal obligations to provide appropriate safety, comfort, and care to residents.

We therefore urge the Department to use its authority to prohibit the inclusion of pre-dispute agreements to arbitrate in nursing home and other long-term care facility residency contracts. Residents are more likely to be cared for properly, as the Department's proposed standards intend, if they retain their legal rights.

We agree with the Department's proposal to prohibit a guardian or other representative from agreeing to binding arbitration for a dispute unless doing so is authorized by state law and the guardian or representative has no interest in the facility; we would go further and require that there be no conflict of interest of any kind, and that the guardian or representative so attest, under penalty of perjury. And we also agree with the Department's proposal to prohibit any agreement to restrict or prevent a resident or representative from informing regulators about dangerous or unhealthy conditions in the facility; we would go further and protect the right to inform the media and the general public. These proposals should be included in addition to the prohibition on pre-dispute arbitration agreements. They should apply even to agreements to arbitrate entered into after the dispute arises.

Infection control and antibiotic stewardship, and medication oversight

Consumers Union strongly supports the proposals relating to antibiotic stewardship, infection control, and related pharmacy services for nursing homes and other long-term care facilities. We recommend that the Department publicly report results from these new requirements, to document infections, antibiotic use and medication irregularities and appropriately inform residents, potential residents, their families, and the public regarding the results of these important patient safety programs. There cannot be effective accountability without public reporting.

These regulations mark a significant step forward in prevention of infections and appropriate use of antibiotics in care for nursing home residents. The proposal notes the staggering dimensions of this problem: "[T]here are between 1.6 and 3.8 million HAIs [health care-acquired infections] in nursing homes every year. Annually, these infections result in an estimated 150,000 hospitalizations, 388,000 deaths, and between $673 million and $2 billion dollars in additional healthcare costs." This is a national tragedy that is likely to touch the life of every American. The Department's modest proposals should move us toward safer homes for the millions of nursing home residents and reduce the death toll from preventable infections.

We strongly support Sections 483.75 and 483.80, which would create a stronger

foundation for infection prevention and surveillance in the nation's nursing homes, by establishing minimum standards that these facilities must meet. Antibiotic resistance is a national crisis. The proposal states that nursing homes are the "next frontier where new antibiotic resistant organisms may emerge and flourish." In our view, nursing homes already are a breeding ground for these deadly organisms, and the vulnerable residents are already the victims. According to a 2014 report from the Centers for Disease Control and Prevention, 27,000 nursing homes had antibiotic resistant infections in 2005, and two out three nursing home residents were receiving at least one course of antibiotics annually. These sections would establish antibiotic protocols and monitoring of antibiotic use -- fundamental steps in preventing health-care-acquired infections and antibiotic resistance. These sections will also integrate infection prevention in nursing home quality-assessment programs; require a designated person, with specified qualifications, to be responsible for infection control ; create infection control policies; and require education and training. All are basic infection prevention practices that nursing homes should have had in place years ago. We strongly support prompt implementation of these regulations to address the significant problem of health-care-acquired infections and antibiotic resistance.

Generally, Section 483.45 would require pharmacy reviews of residents' medical charts every six months, as well as prompt reviews for new residents, those transferred from a hospital or other facility, and during monthly reviews when antibiotics and psychotropic drugs are involved. We support these proposed requirements.. These facilities care for some of the most vulnerable people in our society, who are dependent on professional services that provide reviews of medications, accurate information at transfers, and strict infection prevention protocols.

We have the following specific comments regarding Section 483.45:

- We strongly the requirement that irregularities and inappropriate drugs be reported to the attending physician and the facility medical director and director of nursing, and the requirement that the reports be acted upon, and that the attending physician record that action in the resident's medical chart. This also requires the physician to explain in the chart the reasons that a change in irregular or inappropriate medications was *not* made. These are all critical steps for ensuring that nursing home residents are receiving proper medication.

- Since Section 483.45 is intended to cover antibiotic prescriptions, the definition in subsection (d) of "irregular drugs" should include prescribing antibiotics that are inappropriate for the specific problem being addressed. For example, the antibiotic stewardship program [in Section 483.80 (a)(3)] requires an antibiotic protocol, but this definition of irregular drugs doesn't cover an antibiotic prescribed inappropriately

outside of that protocol (e.g., broad spectrum v. narrow spectrum). Closing the gap in this definition is especially important for an accountable and consistent antibiotic stewardship program that will effective in keeping antibiotic resistance in check and in preventing secondary infections such as those caused by C. difficile.

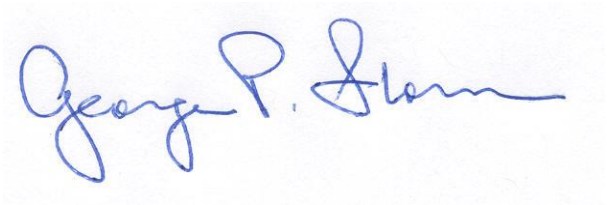
- We support changes proposed in subsection (e) relating to psychotropic drugs. The overuse of these medications is a serious problem in the treatment of elders that requires clear, protective guidelines against overuse. The proposal is a balanced approach that will allow appropriate prescribing of pain medications while protecting against overuse.

- Current medication error language that requires facilities to keep the rate of medication errors under 5% is being relocated to subsection (f) of this Section. While we understand that this is not a new proposal, we believe the clear goal should be that facilities should ensure that patients are protected from *any* medication errors. As written, subsection (f) would only require that a facility ensure protection from "significant" medication errors. We see no reason for the new requirements to accept a 5% medication error rate. The percentage should be lowered, incentives should be strengthened to bring the percentage to zero, and there should be a requirement, here or elsewhere in the regulations, for facilities to document all medication errors and report the rate of medication errors to the Department and ultimately to the public.

Conclusion

We urge the Department, in finalizing these important standards for nursing homes and other long-term care facilities, to incorporate the improvements we recommend above.

Respectfully submitted,



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