December 20, 2017

To: CAGinquiries@cms.hhs.gov

Re: Proposed Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4)

Thank you for the opportunity to submit comments on this proposed Decision Memo. On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments with respect to those aspects that affect those living with advanced illness.

C-TAC is a national non-partisan, not-for-profit organization dedicated to ensuring that all those with advanced illness, especially the sickest and most vulnerable, receive comprehensive, high- quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC is made up of over 140 national and regional organizations including patient and consumer advocacy groups, providers, health plans, faith-based and community organizations, and others who share a common vision of improving advanced illness care in the U.S.

C-TAC's definition of advanced illness is when one or more conditions becomes serious enough that general health and functioning begin to decline, treatment may no longer lead to preferred outcomes, and care oriented toward comfort may take precedence over attempts to cure – a process that extends to the end of life and that for some patients and their families may lead to transition to hospice. It is with that population in mind that we comment on the following aspects of this decision memo.

We applaud requiring a patient shared decision-making (SDM) interaction prior to ICD implantation for certain patients. This is important as patients are often confused[i] about the purpose and nature of these devices. However, we would go further and recommend that any decision aid tool used to facilitate SDM for these devices also include information about when and how they might be deactivated at a future time. Many patients[ii] are unaware of this option, which is unfortunate as some suffer shocks from these devices at the end of life, which are painful and may be counter to their goals of care at that time. Including information about deactivation in the SDM at the time of insertion will help patients make a more truly informed decision about these devices.

Thank you for the opportunity to comment on this decision memo. If you have any

questions, please contact Marian Grant, Senior Regulatory Advisor at C-TAC, at 443-742-8872 or mgrant@thectac.org.

Sincerely,

Marian Grant

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[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4675745/
[ii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5114828/