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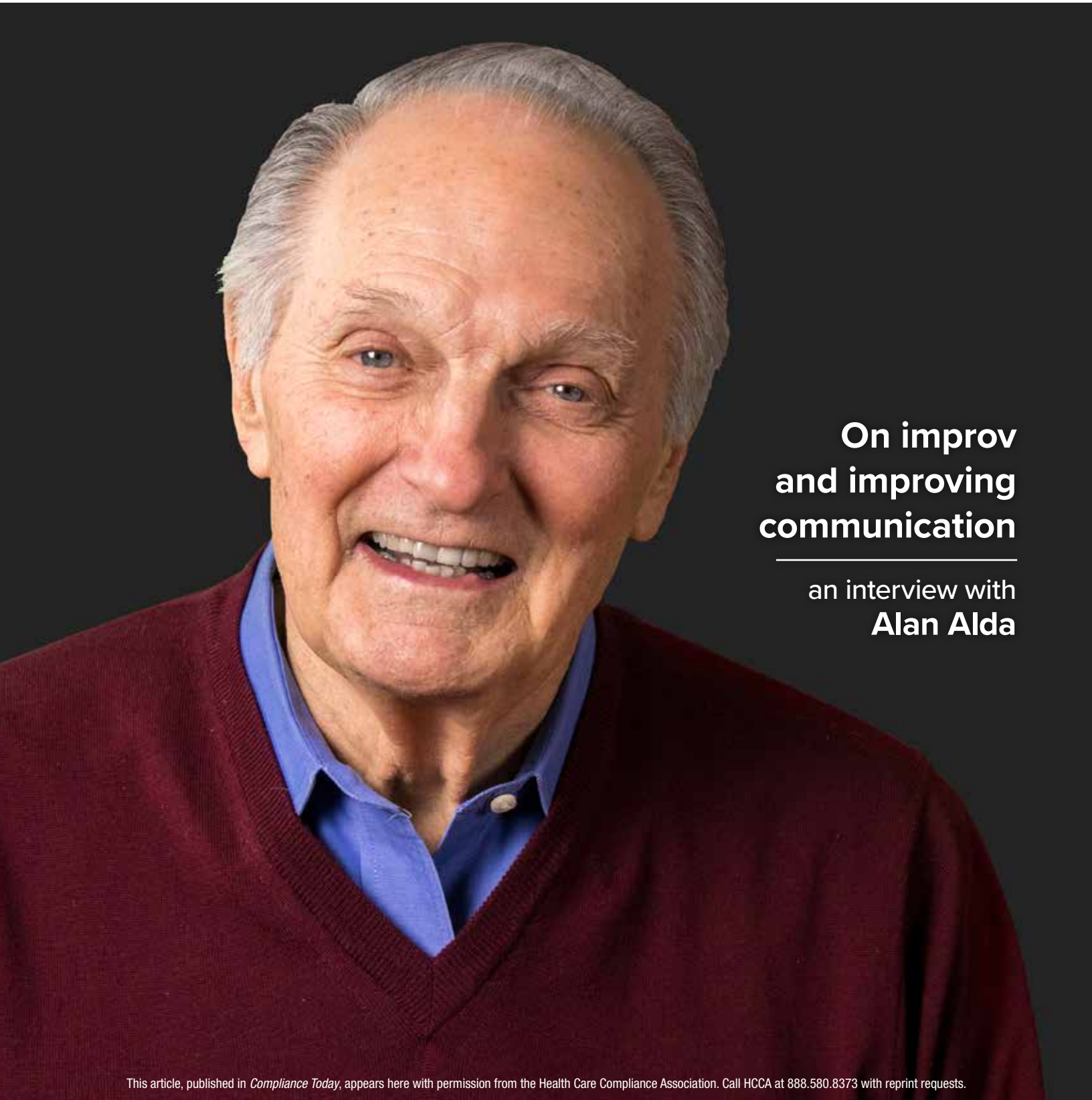
# Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

MARCH 2018



## On improv and improving communication

an interview with
**Alan Alda**

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by Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

# We interrupt your research compliance program!

***Kelly M. Willenberg*** *(Kelly@kellywillenberg.com) is President and CEO of Kelly Willenberg, LLC in Chesnee, SC.*

Interruptions—life's temporary pauses that cause us to stop or take a break from our activity. Research compliance seems to have many of these types of breaks. In 2018, we have to face numerous interruptions for new areas of change. Consider the 2018 Common Rule implementation and what you did to prepare for it. Remember the action items and the list to get your team ready? You had new standard operating procedures, new elements of the informed consent, and the upcoming single Institutional Review Board (IRB) to consider. I remember when asking the question, "Did you check the box?" was an easy answer. With another interruption, we are challenged with keeping up.

Willenberg

Last December, the Food and Drug Administration (FDA) announced the availability of the guidance entitled, "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions." These types of interruptions are not uncommon in the research compliance world.

By modifying the policy, the FDA thought they were helping CMS in determining whether or not an IDE device should be covered (reimbursed) by CMS. It is up to us in the research compliance offices to discern the new rules, because there are rules for CMS that are not necessarily followed by commercial insurance plans or Medicare Advantage Plans. A site must know not only the category designation, but whether the Medicare contractor wants more than the CMS approval available online. Yet another interruption in your normal flow to meet a rule!

2018 will be a busy year for our pharmaceutical sponsors in clinical research. The new General Data Protection Regulation (GDPR) will become effective in all European Union (EU) Member States, so any sponsor doing clinical research must understand the key elements. The GDPR will strengthen the rights of individuals to be better informed about how their data is to be used and set new standards and obligations on using data. Consent, transfer of data, and accountability of data are important in the GDPR for sponsors moving forward. Another interruption?

> I remember when asking the question, "Did you check the box?" was an easy answer.

A pause for a staffing adjustment or a monitor change can seem trivial when you consider the disruptions we must confirm to meet new guidelines or rules imposed by others. "We interrupt your regularly scheduled compliance program to bring you a special bulletin" is just part of the research compliance administrator's every day work life!