

HCCA 20TH ANNUAL COMPLIANCE INSTITUTE

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SESSION 710

TAKING ADVANTAGE OF THE ACO WAIVERS:

DOING IT THE RIGHT WAY AND AVOIDING SUBSTANTIAL RISK

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ACO WAIVERS

PRESENTATION GOALS:

- HOW TO USE ACO WAIVERS TO ACHIEVE THE "TRIPLE AIM"
- APPRECIATING THE LIMITS OF THE ACO WAIVERS
- MAKING SURE USE OF ACO WAIVERS SATISFIES
REQUIREMENTS AND AVOID TRADITIONAL FRAUD
AND ABUSE AND SELF-REFERRAL RESTRICTIONS

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BUT FIRST: DIVERSION #1

WE LOVE ACRONYMS!

- ▶ CHC
- ▶ CMS
- ▶ FTC
- ▶ MSSP
- ▶ HCFA
- ▶ CCO
- ▶ ACA
- ▶ DOJ
- ▶ SSA
- ▶ OIG
- ▶ BHI

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DIVERSION #2

- ▶ WHAT MAKES ONE OF THESE DIFFERENT?
- ▶ ACO
- ▶ PPO
- ▶ PHO
- ▶ PPM

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ACCOUNTABLE CARE ORGANIZATIONS ("ACO")

- ▶ SEC. 3022 OF PPACA, SEC. 1899 OF THE SSA
- ▶ CREATED THE MEDICARE SHARED SAVINGS PROGRAM ("MSSP")
- ▶ MSSP – 3 GOALS:
 - ▶ BETTER CARE FOR INDIVIDUALS
 - ▶ BETTER HEALTH FOR PATIENT POPULATIONS
 - ▶ LOWER GROWTH IN HEALTHCARE EXPENDITURES

- ▶ ACOs VIEWED AS A KEY COMPONENT OF REFORMING THE MEDICARE PROGRAM AND ACHIEVING THESE GOALS

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ACO WAIVERS

- ▶ MSSP "TRIPLE AIM" (SOCIAL SECURITY ACT, SEC 1899(f))
 - ▶ IMPROVE INDIVIDUAL BENEFICIARY'S QUALITY OF CARE
 - ▶ IMPROVE QUALITY OF CARE FOR PATIENT POPULATIONS
 - ▶ LOWER GROWTH OF HEALTHCARE EXPENDITURES

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ACO WAIVERS

- ▶ ACOs CREATURES OF ACA
 - ▶ EXPLICITLY FOR MEDICARE BENEFICIARIES
 - ▶ INTENDED TO ESTABLISH AN INFRASTRUCTURE THAT ACHIEVES THE "TRIPLE AIM" FOR PARTICIPATING BENEFICIARIES
 - ▶ PROVIDE FINANCAL INCENTIVES FOR PHYSICIANS AND OTHER PROVIDERS TO PROVIDE QUALITY CARE AT LOWEST COST
 - ▶ ENCOURAGE BENEFICIARY BEHAVIORS

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ACO WAIVERS

- ▶ ACO PARTICIPATION REQUIREMENTS
 - ▶ 3 YEAR AGREEMENT WITH CMS AND MUST SATISFY REQUIREMENTS FOR:
 - ▶ GOVERNANCE AND LEADERSHIP (PHYSICIAN LEADERSHIP);
 - ▶ PROGRAM INTEGRITY;
 - ▶ TRANSPARENCY; AND
 - ▶ COMPLIANCE PLAN.
- AN ACO IS NOT A PROVIDER/SUPPLIER UNDER THE MEDICARE PROGRAM
 - OR A HIPAA-HITECH "COVERED ENTITY"

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ACO WAIVERS PAYMENT MECHANIMS

- ▶ TRACK 1- ONE SIDED (NO DOWNSIDE LIABILITY)
 - ▶ ACO ABLE TO SHARE IN SAVINGS

- ▶ TRACK 2- TWO SIDED
 - ▶ ACO SHARES IN SAVINGS BUT ALSO LIABLE FOR LOSSES TOO

- ▶ TRACK 3- TWO SIDED
 - ▶ ACO ABLE TO TAKE GREATER RISK/REWARD THAN TRACK 2

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ACO WAIVERS – THE PROBLEM

- ▶ IN ORDER TO ACHIEVE SAVINGS, ACOs NEED TO REVISE THE PATIENT DELIVERY SYSTEM IN ORDER TO:
 - ▶ DEVELOP STANDARD PROTOCOLS
 - ▶ MEASURE QUALITY OF CARE AND OUTCOMES
 - ▶ CONTRACT WITH PROVIDERS THAT CAN PROVIDE QUALITY SERVICES AT THE LOWEST COST
 - ▶ PROVIDE FINANCIAL INCENTIVES TO PHYSICIANS AND OTHERS TO ADOPT THE PROTOCOLS AND USE THE LOW COST PROVIDERS

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ACO WAIVERS – THE PROBLEM (CONT.)

- ▶ FEDERAL HEALTH CARE PROGRAMS' LONG HELD PROHIBITIONS AGAINST-
- ▶ OFFERING, ACCEPTING, SOLICITING, OR PAYING REMUNERATION IN EXCHANGE FOR:
 - ▶ THE REFERRAL OF PATIENTS OR BUSINESS
 - ▶ WITHHOLDING PATIENT TREATMENT
 - ▶ INFLUENCING PATIENT BEHAVIOR
- ▶ PHYSICIAN SELF-REFERRAL ARRANGEMENTS

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ACO WAIVERS- DEVELOPMENT

- ▶ 4/7/2011- CMS AND OIG PUBLISH JOINT NOTICE WITH COMMENT PERIOD – "WAIVER DESIGNS IN CONNECTION WITH THE SHARED SAVINGS PROGRAM AND THE INNOVATION CENTER"
- ▶ PROPOSED WAIVERS TO FRAUD AND ABUSE STATUTES SPECIFIC TO ACOs
- ▶ APPEAR TO PERMIT ACTIVITIES NOT PERMITTED BY A SAFE HARBOR OR STARK EXCEPTION

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ACO WAIVERS - DEVELOPMENT

- ▶ 11/2/2011- CMS AND OIG JOINTLY PUBLISHED AN INTERIM FINAL RULE FOR ACO WAIVERS; 76 FR 67,992
 - ▶ PRE-PARTICIPATION WAIVER
 - ▶ PARTICIPATION WAIVER
 - ▶ SHARED SAVINGS DISTRIBUTIONS WAIVER
 - ▶ PHYSICIAN SELF-REFERRAL LAW WAIVER
 - ▶ PATIENT INCENTIVE WAIVER
 - ▶ PHYSICIAN GAINSHARING
- ▶ 2/12/2015- CMS AND OIG ISSUED "ADDITIONAL WAIVER GUIDANCE"

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ACO WAIVERS - DEVELOPMENT

- ▶ MEDICARE PROGRAM; FINAL WAIVERS IN CONNECTION WITH THE SHARED SAVINGS PROGRAM. 80 FR 66,726 (10/29/2015)
- ▶ FINAL RULE ADOPTS 5 WAIVERS:
 - ▶ PRE-PARTICIPATION WAIVER
 - ▶ PARTICIPATION WAIVER
 - ▶ SHARED SAVINGS DISTRIBUTIONS WAIVER
 - ▶ PHYSICIAN SELF-REFERRAL LAW WAIVER
 - ▶ PATIENT INCENTIVE WAIVER

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ACO WAIVERS - DEVELOPMENT

- ▶ ACO WAIVER FOR PHYSICIAN GAINSHARING ARRANGEMENTS
 - ▶ INCLUDED IN 4/7/2011 INTERIM RULE
 - ▶ DELETED FROM 10/29/2015 INTERIM FINAL RULE, BECAUSE:
 - ▶ WHEN THE INTERIM RULE WAS PUBLISHED "HOSPITALS WERE PROHIBITED FROM KNOWINGLY PAYING PHYSICIANS TO INDUCE THEM TO REDUCE OR LIMIT SERVICES, INCLUDING MEDICALLY *UNNECESSARY* SERVICES. THE STATUTE WAS RECENTLY AMENDED TO PROHIBIT HOSPITALS FROM KNOWINGLY PAYING PHYSICIANS TO INDUCE THEM TO REDUCE OR LIMIT MEDICALLY *NECESSARY* SERVICES."
 - ▶ 80 FR 66,726-727.

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ACO WAIVERS

FINAL RULE ADOPTED

OCTOBER 29, 2015; 80 FR 66,726

FINALIZED 5 WAIVERS

- ▶ PRE-PARTICIPATION WAIVER
 - ▶ PARTICIPATION WAIVER
 - ▶ SHARED SAVINGS DISTRIBUTIONS WAIVER
 - ▶ PHYSICIAN SELF-REFERRAL LAW WAIVER
 - ▶ PATIENT INCENTIVE WAIVER

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ACO WAIVERS – “REASONABLY RELATED”

- ▶ SEVERAL WAIVERS REQUIRE THAT THE ARRANGEMENT MUST BE ***“REASONABLY RELATED TO THE PURPOSES OF THE SHARED SAVINGS PROGRAM”***
- ▶ (i) PROMOTING ACCOUNTABILITY FOR QUALITY COST AND OVERALL CARE OF MEDICARE POPULATION;
- ▶ (ii) MANAGING AND COORDINATING CARE FOR MEDICARE FEE-FOR-SERVICE BENEFICIARIES THROUGH THE ACO; AND
- ▶ (iii) ENCOURAGING INVESTMENT IN INFRASTRUCTURE AND REDESIGNED CARE PROCESSES FOR HIGH QUALITY AND “EFFICIENT SERVICE DELIVERY”

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ACO WAIVERS “REASONABLY RELATED” EXAMPLES

- ▶ PROMOTING EVIDENCE-BASED MEDICINE AND PATIENT ENGAGEMENT;
- ▶ MEETING QUALITY AND COST MEASURE REPORTING REQUIREMENTS;
- ▶ COORDINATING CARE THROUGH TELEMEDICINE AND OTHER TECHNOLOGIES;
- ▶ ESTABLISHING CLINICAL AND ADMINISTRATIVE SYSTEMS FOR THE ACO;
- ▶ COMMUNICATING CLINICAL KNOWLEDGE AND EVIDENCE-BASED MEDICINE TO BENEFICIARIES; AND
- ▶ DEVELOPING STANDARDS FOR BENEFICIARY ACCESS AND COMMUNICATIONS, INCLUDING ACCESS TO MEDICAL RECORDS.
 - ▶ NOTE: NON-ACO BENEFICIARIES ALSO MAY BENEFIT FROM THESE SAME MEASURES

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ACO WAIVERS

EXAMPLES OF WHAT IS NOT "REASONABLY RELATED"

- ▶ REQUIRING PHYSICIANS TO PAY FOR ACCESS TO ACO REFERRALS ("PAY-TO-PLAY" ARRANGEMENTS);
- ▶ SHAM MEDICAL DIRECTOR OR PERSONAL SERVICE ARRANGEMENTS INVOLVING REFERRING PHYSICIANS;
- ▶ PAYMENTS TO INDUCE PHYSICIANS TO STINT ON MEDICALLY NECESSARY CARE;
- ▶ PROVIDING GIFTS TO REFERRING ACO PHYSICIANS, SUPPLIERS, PARTICIPANTS.
- ▶ SUBJECT TO CASE-BY-CASE REVIEW/SAFE HARBOR ANALYSIS

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ACO WAIVERS

PRE-PARTICIPATION WAIVER- ELIGIBILITY

- ▶ MUST BE MAKING "GOOD FAITH" EFFORT TO FORM ACO
- ▶ MUST INCLUDE AT LEAST 1 PARTY ELIGIBLE TO FORM AN ACO
- ▶ DOES NOT COVER ARRANGEMENTS INVOLVING DRUG OR DEVICE MANUFACTURERS, OR DISTRIBUTORS, DME SUPPLIERS, OR "HOME HEALTH SUPPLIERS"
 - ▶ "HOME HEALTH SUPPLIER" = PRIMARILY ENGAGED IN FURNISHING HOME HEALTH SERVICES

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ACO WAIVERS PRE-PARTICIPATION WAIVER

▶ DURATION

- ▶ APPLIES ONLY TO ARRANGEMENTS PART OF A GOOD FAITH EFFORT TO ESTABLISH AN ACO
 - ▶ DURING YEAR PRECEDING AN APPLICATION DUE DATE ("TARGET YEAR") THAT IS ACCEPTED;
 - ▶ IF APPLICATION IS REJECTED BY CMS, UNTIL 6 MONTHS AFTER THE DATE OF THE DENIAL NOTICE; OR
 - ▶ IF ACO DOES NOT SUBMIT APPLICATION DURING TARGET YEAR, EITHER
 - ▶ (a) ON THE TARGET YEAR DUE DATE, OR,
 - ▶ (b) IF IT CAN DEMONSTRATE A LIKELIHOOD OF A SUCCESSFUL SUBMISSION, THE NEXT TARGET YEAR APPLICATION DUE DATE (ONLY AVAILABLE ONCE).

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ACO WAIVERS PRE-PARTICIPATION WAIVER

ADDITIONAL REQUIREMENTS:

1. ACO GOVERNING BODY HAS AUTHORIZED THE ARRANGEMENT
2. DILIGENCE IS DOCUMENTED AND CONTEMPORANEOUS
3. RETAIN DOCUMENTATION FOR 10 YEARS AFTER THE ARRANGEMENT
4. DESCRIPTION OF THE ARRANGEMENT IS PUBLICLY DISCLOSED

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ACO WAIVERS PARTICIPATION WAIVER

DURATION

- ▶ PARTICIPATION WAIVER IS EFFECTIVE ON START DATE OF PARTICIPATION AGREEMENT
- ▶ PARTICIPATION WAIVER TERMINATES ON THE EARLIER OF:
 - ▶ 6 MONTHS FOLLOWING THE EARLIER OF (a) THE EXPIRATION OF THE ACO AGREEMENT, (b) THE ACO VOLUNTARILY TERMINATES THE AGREEMENT, OR
 - ▶ (c) IF CMS TERMINATES THE AGREEMENT, WAIVER PERIOD ENDS ON DATE OF TERMINATION NOTICE.

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ACO WAIVERS PARTICIPATION WAIVER

- ▶ GOVERNING BODY DETERMINES THAT THE ARRANGEMENT IS REASONABLY RELATED TO THE PURPOSES OF SHARED SAVINGS PROGRAM
- ▶ ARRANGEMENT AND AUTHORIZATION ARE CONTEMPORANEOUSLY DOCUMENTED AND MAINTAINED FOR 10 YEARS
 - ▶ DESCRIBES ALL OF THE PARTIES, ITEMS AND SERVICES, AND FINANCIAL TERMS
 - ▶ BASIS FOR BOARD'S DETERMINATION THE ARRANGEMENT IS REASONABLY RELATED TO THE PURPOSES OF THE SHARED SAVINGS PROGRAM
- ▶ ARRANGEMENT IS PUBLICLY DISCLOSED

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ACO WAIVERS PRE-PARTICIPATION & PARTICIPATION WAIVER PUBLIC DISCLOSURE REQUIREMENT

MEDICARE SHARED SAVINGS PROGRAM WAIVERS: ADDITIONAL GUIDANCE (2/12/2015)

- ▶ FOR ARRANGEMENTS AN ACO SEEKS TO FIT WITHIN EITHER WAIVER ONE REQUIREMENT IS PUBLIC DISCLOSURE
- ▶ WHERE: ON THE ACO'S PUBLIC WEB SITE
- ▶ WHEN: W/IN 60 DAYS OF THE DATE OF THE ARRANGEMENT

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ACO WAIVERS PRE-PARTICIPATION & PARTICIPATION WAIVER PUBLIC DISCLOSURE REQUIREMENT (CONT.)

MEDICARE SHARED SAVINGS PROGRAM WAIVERS: ADDITIONAL GUIDANCE (2/12/2015)

- ▶ WHAT NEEDS TO BE DISCLOSED
 - ▶ POSTING IS CLEARLY LABELED;
 - ▶ IDENTIFY ALL OF THE PARTIES;
 - ▶ DATE OF THE ARRANGEMENT;
 - ▶ TYPE OF ITEMS, SERVICES, GOODS OR FACILITIES PROVIDED;
 - ▶ NAME OF ACO;
 - ▶ OTHER IDENTIFYING INFORMATION; AND
 - ▶ ANY MATERIAL AMENDMENT OR MODIFICATION.
 - ▶ **BUT NOT:** FINANCIAL OR ECONOMIC TERMS OF ARRANGEMENT

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ACO WAIVERS SHARED SAVINGS DISTRIBUTION WAIVER

REQUIREMENTS:

1. ACO IS IN GOOD STANDING UNDER ITS PARTICIPATION AGREEMENT;
2. SHARED SAVINGS ARE EARNED BY THE ACO PURSUANT TO THE SHARED SAVINGS PROGRAM
3. SHARED SAVINGS ARE EARNED DURING THE TERM OF THE PARTICIPATION AGREEMENT
4. SHARED SAVINGS ARE-
 - a. SHARED AMONG PARTIES THAT WERE ACO PARTICIPANTS, PROVIDERS, OR SUPPLIERS DURING THE YEAR THE SAVINGS WERE EARNED; AND
 - b. USED FOR ACTIVITIES THAT ARE REASONABLY RELATED TO THE PURPOSES OF THE SHARED SAVINGS PROGRAM

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ACO WAIVERS PHYSICIAN SELF-REFERRAL LAW WAIVER

- ▶ SECTIONS 1128(B)(1) AND (2) OF THE SSA ARE WAIVED FOR ANY FINANCIAL RELATIONSHIP BETWEEN AN ACO, ITS PARTICIPANTS, AND PROVIDERS/SUPPLIERS THAT IMPLICATES THE SELF-REFERRAL STATUTE IF:
 - ▶ 1. ACO IS IN GOOD STANDING UNDER ITS PARTICIPATION AGREEMENT;
 - ▶ 2. FINANCIAL RELATIONSHIP IS REASONABLY RELATED TO THE PURPOSES OF THE SHARED SAVINGS PROGRAM;
 - ▶ 3. FINANCIAL RELATIONSHIP FULLY COMPLIES WITH THE STARK EXCEPTIONS.

WAIVER COMMENCES ON START DATE OF PARTICIPATION AGREEMENT AND ENDS ON EXPIRATION OF PARTICIPATION AGREEMENT OR PARTICIPATION AGREEMENT IS TERMINATED.

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ACO WAIVERS WAIVER FOR PATIENT INCENTIVES

- ▶ ACO IS IN GOOD STANDING UNDER ITS PARTICIPATION AGREEMENT
- ▶ THERE IS A REASONABLE CONNECTION BETWEEN THE ITEMS AND SERVICES AND THE MEDICAL CARE OF THE BENEFICIARY
- ▶ THE ITEMS OR SERVICES ARE IN-KIND
- ▶ THE ITEMS OR SERVICES
 - ▶ ARE PREVENTATIVE CARE, OR
 - ▶ ADVANCE ONE OR MORE OF THE FOLLOWING CLINICAL GOALS
 - ▶ ADHERENCE TO A TREATMENT REGIME
 - ▶ ADHERENCE TO A DRUG REGIME
 - ▶ ADHERENCE TO FOLLOW-UP CARE PLAN OR
 - ▶ MANAGEMENT OF A CHRONIC DISEASE OR CONDITION.

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ACO WAIVERS

LIMITATIONS/QUESTIONS

- APPLY ONLY TO MEDICARE PARTICIPATION ACOs
- MAY BE AVAILABLE WHEN SAFE HARBORS ARE NOT
- NO IMPACT ON STATE LAW RESTRICTIONS
- SHARED SAVINGS DISTRIBUTIONS WAIVER LIMITED TO PAYMENTS RECEIVED FROM CMS FOR SHARED SAVINGS
- DO NOT PROVIDE NFPs EXEMPTION FROM IRC LIMITATIONS

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ACO WAIVERS ANTI-TRUST CONCERNS

- ▶ ACOs, BY THEIR NATURE, INVOLVE COMPETITORS WORKING TOGETHER TO MANAGE CARE, CONTROL COSTS, AND REALIZE A PROFIT
- ▶ REQUIRES SHARING OF PROPRIETARY INFORMATION
- ▶ LOOKS A GREAT DEAL LIKE THE TYPE OF PRICE FIXING/COLLUSION THAT IS GENERALLY PROHIBITED UNDER FEDERAL AND STATE ANTI-TRUST LAWS

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ACO WAIVERS ANTI-TRUST CONCERNS

- ▶ "STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS PARTICIPATING IN THE MEDICARE SHARED SAVINGS PROGRAM"
 - ▶ FINAL POLICY STATEMENT – ISSUED BY FTC AND DOJ
 - ▶ 76 FR 67,026 (10/28/2011) ("JOINT POLICY STATEMENT")

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ACO WAIVERS JOINT POLICY STATEMENT

- ▶ “RECENT COMMENTARY SUGGESTS THAT SOME HEALTH CARE PROVIDERS ARE LIKELY TO CREATE AND PARTICIPATE IN ACOs THAT SERVE BOTH MEDICARE BENEFICIARIES AND COMMERCIALLY INSURED PATIENTS”
- ▶ ACOs THAT SATISFY THE MSSP REQUIREMENTS “ARE REASONABLY LIKELY TO BE BONA FIDE ARRANGEMENTS INTENDED TO IMPROVE THE QUALITY, AND REDUCE THE COSTS, OF PROVIDING” HEALTH CARE ITEMS AND SERVICES

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ACO WAIVERS JOINT POLICY STATEMENT

- ▶ DOJ/FTC WILL “TREAT JOINT NEGOTIATIONS WITH PRIVATE PAYERS AS REASONABLY NECESSARY TO AN ACOs PRIMARY PURPOSE OF IMPROVING HEALTH CARE DELIVERY, AND WILL AFFORD RULE OF REASON TREATMENT TO AN ACO THAT MEETS CMS’S ELIGIBILITY REQUIREMENTS”
- ▶ RULE OF REASON = BALANCING PROCOMPETITIVE IMPACT OF CLINICAL/FINANCIAL INTEGRATION AGAINST ANTICOMPETITIVE IMPACT
 - ▶ IN CONTRAST, PER SE ANALYSIS LOOKS ONLY TO SEE IF THE PARTIES’ ACTIONS RESTRICT COMPETITION/INJUR THE PUBLIC

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ACO WAIVERS JOINT POLICY STATEMENT

▶ LIMITATIONS:

- ▶ DOES NOT APPLY TO MERGERS
- ▶ DOES NOT APPLY TO SINGLE, FULLY INTEGRATED ENTITIES

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ACO WAIVERS SUMMARY

▶ 5 WAIVERS

- ▶ PRE-PARTICIPATION
- ▶ PARTICIPATION
- ▶ SHARED SAVINGS DISTRIBUTIONS
- ▶ PHYSICIAN SELF-REFERRALS
- ▶ PATIENT INCENTIVES

- ▶ **FTC/DOJ JOINT POLICY STATEMENT**
 - ▶ RULE OF REASON
 - ▶ MSSP ACOs & PRIVATE PAYER ACOs

- ▶ **NO PREEMPTION**
 - ▶ **NO HIPAA-HITECH RELIEF**

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ACO WAIVERS FINALE

- ▶ "A GOOD SPEECH SHOULD BE LIKE A WOMAN'S SKIRT;
LONG ENOUGH TO COVER THE SUBJECT AND SHORT
ENOUGH TO CREATE INTEREST"

- WINSTON CHIRCHILL

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QUESTIONS?