CHAPTER 10
IOWA GET SCREENED: COLORECTAL CANCER PROGRAM

641—10.1(135) Purpose. The Iowa get screened (IGS): colorectal cancer program was established in 2009 through a cooperative agreement with the Centers for Disease Control and Prevention and is administered by the department. The goal of the IGS program is to reduce the incidence, mortality and prevalence of colorectal cancer in Iowa by increasing the number of men and women who receive colorectal cancer screenings. Through the program, fecal immunochemical tests (FITs) and colonoscopies will be provided to eligible Iowans. Along with providing screenings, the program also facilitates supportive services and referral for diagnosis and treatment to Iowans with abnormal screening results. Iowans who are eligible to enter the program must be 50 to 64 years of age, be underinsured or uninsured, have incomes of up to 250 percent of the federal poverty level (FPL) and have an average or increased risk for developing colorectal cancer.
[**ARC 0060C**, IAB 4/4/12, effective 5/9/12]

641—10.2(135) Definitions. For purposes of this chapter, the following definitions apply:

"Advanced registered nurse practitioner" means an individual licensed to practice under 655—Chapter 7.

"Case management" means establishing, brokering and sustaining a system of available clinical and essential support services for all individuals enrolled in the program.

"Colon" means large intestine or large bowel.

"Colonoscope" means a thin, flexible tube that takes pictures of the colon and rectum during a colonoscopy.

"Colonoscopist" means a licensed provider who administers a colonoscopy.

"Colonoscopy" means a visual examination of the inner surface of the colon by means of a colonoscope.

"Colorectal cancer," "colon cancer" or *"CRC"* means cancer that starts in the colon or the rectum.

"Colorectal cancer data elements" or *"CCDE"* means a set of standardized data elements developed by the Centers for Disease Control and Prevention, Division of Cancer Prevention and Control, to ensure that consistent and complete information is collected on participants whose screening or diagnosis was paid for through the IGS program with federal funding.

"Department" means the Iowa department of public health.

"Double-contrast barium enema" means an X-ray examination of the entire large intestine (colon) and rectum in which barium and air are introduced gradually into the colon by a rectal tube.

"Eligibility criteria" means a set of questions that a potential participant is asked to ensure the participant meets program qualifying standards including targeted age, income guidelines, level of risk for colorectal cancer and screening determination guidelines. Qualifying standards are outlined in the CDC's Colorectal Control Cancer Program Policies and Procedures and are based on recommendations from the United States Preventive Services Task Force (USPSTF).

"Endoscopist" means a physician who is licensed to perform a visual inspection of any cavity of the body by means of an endoscope.

"Familial adenomatous polyposis" or *"FAP"* means an inherited colorectal cancer syndrome and accounts for 1 percent of all cases of colorectal cancer. "Familial" means FAP runs in families; "adenomatous" means the type of polyps detected in the colon and small intestine that may become cancerous; and "polyposis" means the condition of having multiple colon polyps. The gene for FAP is on the long arm of chromosome 5 and is called the APC gene.

"Family history" means that a person's close relatives (parents, siblings or children) have had colorectal cancer and, therefore, the person is somewhat more likely to develop that type of cancer, especially if the family member developed the cancer at a young age. If many family members have had colorectal cancer, the chances that the person will develop colorectal cancer increase even more.

"Fecal immunochemical test" or *"FIT"* means the primary screening method for the IGS program to test for hemoglobin in the feces, a possible sign of colorectal cancer.

"Federally qualified health center" or *"FQHC,"* referred to in Iowa as a community health center or "CHC," means a federally funded nonprofit health center or clinic that serves medically underserved areas and populations. Federally qualified health centers provide primary care services regardless of ability to pay. Services shall be provided on a sliding fee scale based on ability to pay. The IGS program utilizes community health centers to provide services to target populations.

"Final diagnosis" means the process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination and review of laboratory data.

"Health care provider" means any physician, advanced registered nurse practitioner, or physician assistant who is licensed by the state of Iowa and provides care to IGS-enrolled participants.

"Hereditary nonpolyposis colorectal cancer" or *"HNPCC"* means an inherited colorectal cancer syndrome and accounts for 5 percent of all cases of colorectal cancer. "Hereditary" means HNPCC is inherited or can be passed from parent to child; "nonpolyposis" contrasts HNPCC to the inherited condition FAP where hundreds to thousands of polyps develop in the colon; "colorectal cancer" is the most frequent cancer that develops in these families. Patients with HNPCC have an 80 percent chance of developing colorectal cancer.

"Informed consent" means the participant has signed the IGS informed consent and release of medical information form and therefore voluntarily agrees to participate and receive colorectal services and appropriate follow-up through the IGS program. Consent for services can be canceled at any time by the participant.

"In-reach" means the method that will be used in the local program to recruit participants. In-reach targets existing clients through the Iowa care for yourself program and federally qualified health centers.

"Iowa care for yourself program" or *"IA CFY program"* means a program that provides breast and cervical cancer screening, diagnostics and cardiovascular-related intervention services to low-income, underinsured or uninsured women 40 to 64 years of age. The IA CFY program integrates program services, as possible, with the IGS program. Some IA CFY program participants have been enrolled through in-reach activities into the IGS program.

"Iowa get screened: colorectal cancer program" or *"IGS program"* means the state program funded through the federal Colorectal Cancer Control Program (CRCCP). This program requires policy and systems change, public education and awareness and limited screening activities. The IGS program has been made possible in Iowa through a cooperative agreement awarded to the department through the competitive bid grants procurement process by the United States Department of Health and Human Services, Division of the Centers for Disease Control and Prevention.

"Large intestine" means the last part of the digestive tract. The large intestine is divided into sections including the ascending which begins at the cecum on the right side, the transverse which is the horizontal section, and the descending which is on the left side and includes the sigmoid and the rectum. The primary function of the large intestine is the absorption of water and the formation and collection of feces.

"Local program" means the entity or facility in which IGS services are being offered through a contractual agreement with the department.

"Local program coordinator" means the individual within a local program who is providing services to a participant.

"Medical advisory board" or *"MAB"* means the body that provides oversight of the quality of screening services delivered through the IGS program.

"Oncologist" means a specialist physician who treats or studies the physical, chemical and biologic properties and features of a neoplasm, including causation, pathogenesis and treatment.

"Participant" means an individual enrolled in the IGS program to receive colorectal cancer screening services in accordance with the United States Preventive Services Task Force (USPSTF) recommendations.

"Pathologist" means a specialist physician who identifies diseases by studying cells and tissues under a microscope.

"Patient navigator" means the individual who identifies and coordinates resources for a participant with a screening diagnosis of colorectal cancer who may require physical, emotional, financial or other

support through the cancer journey. Navigation services are provided through a cooperative agreement with the American Cancer Society.

"Physician" means an individual licensed to practice under Iowa Code chapter 148.

"Physician assistant" means an individual licensed to practice under Iowa Code chapter 148C.

"Polyp" means a growth from a mucous membrane commonly found in organs such as the rectum, the uterus and the nose. Certain types of polyps, such as adenomas, may develop into cancer.

"Precancerous" means a condition that may become or is likely to become cancer.

"Primary care provider" means a health care provider who provides definitive care to a patient at the point of first contact and takes continuing responsibility for providing the patient's care.

"Provider agreement" means a signed cooperative agreement between the department and another party, for example, a health care provider.

"Radiologist" means a specialist physician trained in creating and interpreting pictures of areas inside the body. The pictures are produced with X-rays, sound waves or other types of energy.

"Rectum" means the last part of the large intestine where stool is stored prior to evacuation through the anus (external opening of the digestive system).

"Referral" means directing program participants with abnormal screening results to appropriate resources for follow-up action.

"Screening" means the search for disease, such as cancer or precancerous polyps in people without symptoms.

"Secondary complication" means an additional problem that arises following a procedure, treatment or illness.

"Surveillance" means a periodic colonoscopy as recommended by a physician on a case-by-case basis for participants with a prior history of adenoma(s) or colorectal cancer in accordance with USPSTF recommendations. The purpose of surveillance is to rescreen and remove polyps that were missed on the initial colonoscopy or that developed in the interval since the previous colonoscopy.

"Underinsured" means an individual with income at 250 percent of the federal poverty guideline or lower with health insurance that has unreasonably high copayments, deductibles or coinsurance.

"United States Preventive Services Task Force" or *"USPSTF"* means an independent panel of nonfederal health care experts that evaluates the latest scientific evidence on clinical preventive services and then sets recommendations for preventive services including colorectal cancer screening. These recommendations by USPSTF are the guidelines that are followed for recommended colorectal cancer screening by the IGS program.

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641—10.3(135) Components of the Iowa get screened (IGS): colorectal cancer program. The program shall include the following key components:

10.3(1) Program and fiscal management shall be conducted by ensuring strategic planning, implementation, coordination, integration and evaluation of all programmatic activities and administrative systems, as well as the development of key communication channels and oversight mechanisms to aid in these processes. Program management shall ensure that infrastructure adequately supports service delivery.

10.3(2) Service delivery to screen for colorectal cancer for participants enrolled in the IGS program shall be provided by local program coordinators and enrolled heath care providers through contractual arrangements.

a. The IGS program provides reimbursement for the following screening tests, procedures, preparations and tissue analyses when those services are provided by a participating health care provider who has a provider agreement with the IGS program. Payment is based on Medicare Part B participating provider rates (Title XIX).

(1) Fecal immunochemical tests annually;

(2) Colonoscopy every 10 years from initial screen or as prescribed by a physician for surveillance in accordance with USPSTF recommendations;

(3) Biopsy/polypectomy during a colonoscopy;

(4) Bowel preparation;

(5) Moderate sedation for colonoscopy;

(6) One office visit related to IGS program-covered colorectal cancer tests;

(7) One office visit related to colorectal cancer follow-up diagnostic test results;

(8) Total colon examination with either colonoscopy (preferred) or double contrast barium enema if medically prescribed by doctor;

(9) Pathology services.

b. The IGS program does not provide reimbursement for the following:

(1) Screening tests requested at intervals sooner than recommended by the USPSTF;

(2) CT colonography (or virtual colonoscopy) as a primary screening test;

(3) Computed tomography scans (CT or CAT scans) requested for staging or other purposes;

(4) Surgery or surgical staging, unless specifically required and approved by the IGS program's MAB to provide a histological diagnosis of cancer;

(5) Any treatment related to the diagnosis of colorectal cancer;

(6) Any care or services for complications that result from screening or diagnostic tests provided by the IGS program;

(7) Medical evaluation of symptoms that make individuals at high risk for CRC;

(8) Diagnostic services for participants who had an initial positive screening test performed outside of the program;

(9) Management and testing (e.g., surveillance colonoscopies and medical therapy) for medical conditions, including inflammatory bowel disease, ulcerative colitis or Crohn's disease;

(10) Genetic testing for participants who present with a history suggestive of a hereditary nonpolyposis colorectal cancer (HNPCC) or familial adenomatous polyposis (FAP);

(11) Use of propofol as anesthesia during endoscopy, unless specifically required and approved by the IGS program's MAB in cases where the participant cannot be sedated with standard moderate sedation; and

(12) Treatment for colorectal cancer.

c. A local program that has a signed contract with the IGS program shall be responsible for the following:

(1) Recruitment of participants;

(2) Eligibility determination;

(3) Enrollment;

(4) Patient support services;

(5) Tracking of follow-up care;

(6) Documentation and data reporting; and

(7) Recall of participants who remain eligible for continued services.

d. Local program coordinators must use a case management services approach throughout the screening process to ensure that all participants:

(1) Receive program information and colorectal cancer educational materials;

(2) Are assisted, according to each participant's need, to reduce barriers to screening including, for example, fears, cultural beliefs, language, transportation, understanding of information, and insurance enrollment;

(3) Receive guidance throughout the screening, diagnostic and treatment processes;

(4) Understand colorectal cancer screening procedures and health care provider recommendations;

(5) Receive appropriate services according to diagnosis including follow-up; and

(6) Have the opportunity to get questions answered throughout the process.

e. A health care provider that has a provider agreement with the department shall be subject to the following provisions:

(1) The health care provider agrees that reimbursement of procedures and services provided shall not exceed the amount that would be paid under Medicare Part B participating provider rates of Title XVIII of the Social Security Act.

(2) The health care provider shall provide the participant and local program coordinator timely colorectal cancer screening results and follow-up recommendations.

(3) The gastrointestinal health care provider shall submit pathology specimens to a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory for processing.

(4) The health care provider shall practice according to the current standards of medical care for colorectal cancer early detection, diagnosis and treatment.

(5) The health care provider or entity shall submit universal claim forms, originals of the HCFA 1500 or the UB 92, for reimbursement of IGS program-covered services in accordance with the provider agreement.

(6) The health care provider may deliver services in a variety of settings. Service delivery shall include:

1. Working with local coordinators as they refer IGS program participants to provide follow-up or initial colorectal cancer screening services;

2. Providing a point of contact for program communication with the department to relay information that may include updating data, follow-up information and final diagnosis;

3. Providing screening services for a specific geographic area; and

4. Providing referral and follow-up for participants with abnormal screening results.

(7) The health care provider shall ensure compliance with this chapter and other terms and conditions included in the provider agreement or contract.

10.3(3) IGS program and contracted local program staff shall conduct referral, tracking and follow-up utilizing a Web-based data system to monitor each enrolled participant's receipt of screening, rescreening and diagnostic procedures.

a. The enrolled participant shall be notified within 30 days of the screening service by contracted local program staff or the enrolled health care provider of the results of the service, whether the results are normal, benign or abnormal.

b. The contracted local program shall use the IGS program data system to enter appropriate and timely clinical services, including screening and diagnostic test results, follow-up, and completion of screening services.

c. If the enrolled participant has an abnormal colorectal cancer screening test, the health care provider or local coordinator shall provide to the participant a comprehensive referral directing the participant to appropriate additional diagnostic or treatment services. When the results of a FIT screen are positive, the local coordinator shall work with the participant and enrolled health care provider to schedule a colonoscopy.

d. The local program coordinator shall follow up with the provider to obtain results if not provided in a timely manner.

e. IGS program staff shall follow up with the local program coordinator if results have not been entered in the IGS data system in a timely manner.

10.3(4) If treatment services are needed, the participant's health care provider may perform a consultation in order to educate the participant about treatment options. If more than two office visits are warranted for a participant throughout the screening cycle, subsequent office visits must be authorized by IGS program staff.

10.3(5) IGS program staff shall use quality assurance and process improvement techniques including use of established standards, systems, policies and procedures to monitor, assess and identify practical methods for improvement of the IGS program and its components. Quality assurance and process improvement are integral components of the IGS program and contribute to program success. As part of the vision, to reduce morbidity and mortality from colorectal cancer, high-quality, timely participant services are essential. IGS program requirements and monitoring activities shall include:

a. Professional licensure and accreditation. Health facilities and health care providers must be currently licensed or accredited to practice in the state of Iowa.

b. Reporting standards. Radiological, laboratory and pathology and other results must be reported according to national standards.

c. Standards for adequacy of follow-up. Data reports shall track appropriate and timely short-term, diagnostic and rescreening services.

d. A case management services approach. Local program staff shall follow the participants through the colorectal cancer screening process from the first contact to final diagnosis and as needed for referral to treatment and patient navigation services. Local program staff shall be responsible for documenting these activities as described in paragraph 10.3(2)*"d."*

e. Accurate data collection and documentation.

(1) Colorectal cancer data elements (CCDEs) are reported to CDC semiannually by the department.

(2) Site visits are conducted at local program sites to provide technical assistance, give feedback on program performance, evaluate case management process and if needed conduct a walk-through of current services to provide feedback.

f. Evaluation. Workplans shall be reviewed and surveys conducted in the community and with program partners. Reports on progress and face-to-face meetings shall be conducted routinely and on an as-needed basis to assess how the IGS program is meeting CDC program objectives.

g. Process improvement and systems change activities.

h. Adherence to CDC policies and guidelines.

i. Approval and utilization of additions to the local program allowable procedures list.

10.3(6) Professional development shall be provided by the IGS program and contracted local program staff through a variety of channels including educational activities that enable professionals to perform their jobs competently, to identify needs and resources, and to ensure that health care delivery systems provide appropriate clinical outcomes for colorectal cancer screening services.

10.3(7) The IGS program and contracted local program staff shall provide in-reach education and recruitment that involve the systematic design and delivery of clear and consistent messages about colorectal cancer (CRC) and the benefits of early detection using a variety of methods and strategies. In-reach activities shall focus on men and women who have never or rarely been screened for CRC and shall work toward the removal of barriers to care (e.g., by providing respite care, interpreter services and transportation) through collaborative activities with other community organizations. In-reach shall be targeted toward the participants already being served through the IA CFY program and patients at FQHCs. Public education and outreach activities for community awareness of CRC are supported and mandatory for the project.

10.3(8) The IGS program may develop coalitions and partnerships to establish a common agreement for sharing resources and responsibilities to achieve the common goal of reducing colorectal cancer mortality.

10.3(9) The IGS program shall conduct surveillance utilizing continuous, proactive, timely and systematic collection, analysis, interpretation and dissemination of colorectal cancer screening prevalence, survival and mortality rates. Studies shall be conducted utilizing minimum data elements and other data sources to establish trends of disease, diagnosis, treatment, and research needs. IGS program planning, implementation and evaluation shall be based on the data.

10.3(10) Evaluation by the IGS program evaluator shall be conducted through documentation of services, operation processes at the state and local program levels and outcomes of the IGS program. The evaluation shall include face-to-face interviews with state and local IGS program staff involved in IGS program delivery. IGS program evaluation shall include suggestions to help IGS and local program staff meet the recommendations as set in the CRCCP program manual. Recommendations shall then be incorporated into the program workplan by the state staff.

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641—10.4(135) Medical advisory board. The medical advisory board or MAB is made up of a diverse group of professionals (e.g., primary care providers, nurses, endoscopists, oncologists, pathologists, radiologists, coordinators, patient navigators and the IGS program evaluator) who offer their expertise on issues including enrollment, screening, diagnosis and treatment.

10.4(1) The MAB provides oversight of the quality of screening services delivered. MAB members may participate in other IGS program activities including colorectal cancer awareness month activities and education projects.

10.4(2) The primary role of the MAB is to:

a. Assist in the establishment of IGS program eligibility and service delivery criteria (e.g., defining underinsured, establishing guidelines for diagnostic testing, surveillance intervals, etc.);

b. Monitor quality of screening, rescreening, diagnostic and surveillance services;

c. Assist with identification of resources for treatment and referral of individuals who are ineligible for the program;

d. Provide direction on IGS program policy development and data collection; and

e. Approve additions to the IGS program allowable procedures list, as needed.

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641—10.5(135) Participant eligibility criteria. An applicant for the IGS program must satisfy the criteria outlined in this rule. If an applicant does not meet these criteria, the applicant shall be provided information by contracted local program staff regarding IowaCare, free care or sliding-fee clinics available in the area in which the applicant lives.

10.5(1) *Age.* Individuals 50 through 64 years of age shall be the target population to receive colorectal cancer screening.

10.5(2) *Income.*

a. The IGS program income guidelines are based upon 250 percent of the federal poverty level (FPL), which is set annually by the Centers for Medicare and Medicaid Services (CMS). New IGS program income guidelines will be adjusted following any change in CMS guidelines.

b. Self-declaration of income may be accepted.

c. Eligibility shall be based on net income for the household.

d. Assets shall not affect income status and shall not be counted when eligibility under the IGS program is determined.

10.5(3) *Insurance.*

a. The IGS program shall determine individuals to be uninsured if they do not have health insurance coverage.

b. The IGS program shall determine individuals to be underinsured if they have health insurance with unreasonably high copayments, deductibles or coinsurance or the insurance does not cover the IGS program's covered services.

c. Individuals who have Medicaid or Medicare Part B are not eligible. Individuals who have IowaCare, Medicaid with spend down, or Iowa family planning network may be eligible.

10.5(4) *Residency.*

a. Individuals must reside in the state of Iowa.

b. Individuals shall have an established address and contact information as needed for program staff to provide screening results, rescreens, and follow-up services.

10.5(5) *Risk level.* Individuals with an average or increased risk for developing colorectal cancer as defined by the recommendations of the USPSTF may qualify for IGS program services.

10.5(6) *Ineligible.* The IGS program does not provide coverage for:

a. Individuals with Medicare Part B coverage.

b. Individuals 49 years of age and younger.

c. Individuals 65 years of age and older.

d. Individuals who do not have a primary care provider.

e. Individuals at high risk for developing colorectal cancer. Individuals at high risk include:

(1) A genetic diagnosis of familial adenomatous polyposis (FAP) or hereditary nonpolyposis colorectal cancer (HNPCC),

(2) A clinical diagnosis or suspicion of FAP or HNPCC, or

(3) A history of inflammatory bowel disease (ulcerative colitis or Crohn's disease).

f. Individuals experiencing the following gastrointestinal symptoms:

(1) Rectal bleeding, bloody diarrhea, or very dark blood in the stool within the past six months;
(2) Prolonged change in bowel habits;
(3) Persistent/ongoing abdominal pain;
(4) Recurring symptoms of bowel obstruction; or
(5) Significant unintentional weight loss.

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641—10.6(135) Participant application procedures for IGS program services.

10.6(1) *Enrollment.* After an individual is determined eligible for services and agrees to participate in the IGS program, the following provisions shall apply:

a. A prospective participant must complete the Informed Consent and Release of Medical Information form and submit it to the local program coordinator in order to become enrolled in the program and be considered a program participant. The date on the signed form shall be the participant's enrollment date.

b. Upon enrollment, the participant shall be eligible for services for 12 months beginning from the date of enrollment, subject to restrictions in funding and program coverage as provided in subrules 10.6(2), 10.6(3) and 10.7(1).

10.6(2) *Reenrollment.*

a. A participant's continued eligibility for IGS program coverage shall be determined annually.

b. The IGS local program coordinator shall reenroll the participant in the program no more than 30 days prior to the end of the 12-month coverage period in accordance with USPSTF guidelines or a physician's recommendation.

c. When a participant reenrolls, the participant must complete, sign and return the consent and release form to the local program coordinator before receiving any further services.

10.6(3) *Termination of enrollment.* The IGS program shall terminate a participant's enrollment if the participant:

a. Requests termination from the program;

b. No longer meets the criteria set forth in rule 641—10.5(135);

c. Does not return a signed IGS program consent and release form; or

d. Refuses to receive screening and diagnostic services through an IGS program health care provider.

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641—10.7(135) Priority for program expenditures.

10.7(1) In the event the IGS program director certifies that there are inadequate funds to meet participants' needs, either attributable to a reduction in federal funding from the CDC or to a projected enrollment of participants in excess of anticipated enrollment, the program director may restrict new applicants' participation in the IGS program. First priority shall be given to individuals who have never been screened for CRC.

10.7(2) In the event that the financial demand abates, the program director shall withdraw the financial shortfall certification, at which time the individual shall be eligible for program services in accordance with rule 641—10.5(135).

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641—10.8(135) Right to appeal. If an individual disagrees with or is dissatisfied with IGS program eligibility, the covered-service determination or the decision of the IGS program, the individual has the right to appeal the decision or action.

10.8(1) The appeal shall be in writing and shall be submitted within ten working days of the decision or action to the local program staff with whom the individual has been working.

10.8(2) The local program staff shall contact an IGS program staff person with the information regarding the appeal within three business days.

10.8(3) IGS program staff shall confer with the bureau chief for the IGS program at the department and provide a decision to the local program staff within five business days. A decision made by IGS

program staff shall be delivered by telephone, if possible, to the individual making the appeal and shall be followed by a written notification of the decision. The decision of IGS program staff shall be considered a final agency decision in accordance with Iowa Code chapter 17A.
[**ARC 0060C**, IAB 4/4/12, effective 5/9/12]

641—10.9(135) Colorectal cancer treatment. The IGS program does not pay for colorectal cancer treatment services. A participant will be assisted with enrolling in the IowaCare program, in the event treatment services are needed. If a participant needs treatment, the local program coordinator will refer the participant to an American Cancer Society patient navigator to identify and coordinate resources for the participant who may require physical, emotional, financial or other support through the cancer journey. The patient navigator and IGS program staff will work together to assist a participant needing treatment. It is an expectation of the cooperative agreement that a participant gets help obtaining treatment services free or at an affordable cost based on the participant's annual income and ability to pay for the services.
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These rules are intended to implement Iowa Code sections 135.11(1) and 135.39 and 42 U.S.C. Section 241(a), as amended.

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